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EXAMINING THE ATTITUDES AND BELIEFS OF FAMILY PHYSICIANS TOWARD THE USE OF CONTROLLED-RELEASE OPIOIDS FOR THE TREATMENT OF CHRONIC NON-MALIGNANT PAIN

Committee:

Carolyn M. Brown, Co-Supervisor

Karen L. Rascati, Co-Supervisor

Jamie C. Barner, Committee

Andrew C. Eisenberg, Committee

James P. Wilson, Committee

EXAMINING THE ATTITUDES AND BELIEFS OF FAMILY PHYSICIANS TOWARD THE USE OF CONTROLLED-RELEASE OPIOIDS FOR THE TREATMENT OF CHRONIC NON-MALIGNANT PAIN

by

Esmond Donlee Nwokeji, B.A.; M.B.A.

Dissertation

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DEDICATION

I dedicate this dissertation to my family and friends, especially my parents, Don and Cathie Nwokeji, for instilling the importance of hard work and a desire to always succeed.

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We are reminded by the Greek poem titled “Ithaka,” by Constantine Cavafy, that it is often the voyage and the adventures along the way that are important, and not only the final destination itself. The journey during this dissertation process has truly been an experience of determination and self-awareness. I would not have been able to complete this extraordinary goal without help from a number of important individuals. I would like to thank both of my co-supervisors, Carolyn Brown and Karen Rascati for their endless patience and encouragement in helping me to complete this project. Their guidance has been invaluable during the research process and my graduate career. Also, I would like to thank my committee for their unique contributions and support. Jamie Barner’s ability to keep me grounded in thinking about the basic reasoning behind research methodology and James Wilson’s constant reminder to understand the bigger picture of the project were critical in my progress. Further, Andrew Eisenberg’s practical experience and support enabled me to make this project a success.

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EXAMINING THE ATTITUDES AND BELIEFS OF FAMILY PHYSICIANS TOWARD THE USE OF CONTROLLED-RELEASE OPIOIDS FOR THE TREATMENT OF CHRONIC NON-MALIGNANT PAIN

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Co-Supervisors: Carolyn M. Brown and Karen Rascati

The purpose of this dissertation was to use a theoretical model to examine family physicians' willingness to prescribe controlled-release opiate analgesics (CR opioids) to patients with moderate to severe chronic non-malignant pain (CNMP). The study explored the utility of the Theory of Planned Behavior (TPB) constructs (attitude, subjective norm, and perceived behavioral control), in addition to recent past behavior (RPB), in predicting physicians' willingness to prescribe CR opioids to patients with CNMP.

A web-based survey was developed from three structured focus group interviews, pretested, and e-mailed to 2,750 Texas family physicians. Based on responses from 267 physicians, the TPB constructs were significant predictors in assessing family physicians' willingness to prescribe CR opioids for CNMP, accounting for 39 percent of the variance. Overall, two-thirds of physicians (N=179) indicated they were willing to prescribe CR opioids for CNMP. The attitude construct was found to be a key determinant of physicians' willingness to prescribe. Physicians holding unfavorable attitudes tended to believe that prescribing CR opioids for CNMP would lead to patient abuse, addiction, and regulatory scrutiny. The subjective norm construct was also a significant predictor of physicians' willingness. In general, a majority of physicians indicated that they were

more likely to be influenced by regulatory agencies, pain specialty groups, other primary care physicians, and their patients when deciding whether to prescribe CR opioids for CNMP. The perceived behavioral control construct was also a significant predictor. Physicians indicated that possessing more knowledge in pain management, additional evidence-based studies, and access to pain management tools would improve their level of control over prescribing CR opioids for CNMP. The inclusion of recent past behavior significantly increased the explanatory power of the study model to 57 percent.

In summary, this study identified some key factors that explained family physicians' willingness to prescribe CR opioids for moderate to severe CNMP. Attitude, subjective norm, perceived behavioral control, and recent past behavior were strong predictors of physicians' willingness. Factors identified from this study should be targeted to increase awareness and reduce the impact of barriers that affect prescribing of CR opioids for CNMP.

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DEFINITIONS

The following definitions were provided from a consensus document from the American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine (Consensus Document AAPM APS ASAM, 2001; Evans *et al.*, 2003b).

Addiction – "A primary, chronic, neurobiological disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations; addiction is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving."

Chronic non-malignant pain (CNMP) – Traditionally described as pain persisting for longer than three to six months beyond the usual course of an acute illness, or the time required for an injury to heal. This type of pain may also be associated with a persistent pathologic process or pain recurring at intervals of months or years.

Controlled-release opioids (CR opioids) – Also known as "sustained-release," "extended-release," or "long-acting" opioids, this group of opiate analgesics is considered to provide analgesia in the same manner as immediate-release (short-acting) opioids but over longer periods of time.

Physical dependence – "A state of adaptation that is manifested by a drug class specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist."

Tolerance – "A state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time."

ACRONYMS AND ABBREVIATIONS

The following is a list of acronyms and abbreviations that are used throughout the dissertation manuscript.

A_o - Attitude

AAFP - American Academy of Family Physicians

AAPM - American Association of Pain Medicine

APS - American Pain Society

B - Behavior

b - Behavioral Beliefs

BI - Behavioral Intention

CE - Continuing Education

CNMP - Chronic Nonmalignant Pain

CNS - Central Nervous System

CR opioid - Controlled-release opioid

DEA - Drug Enforcement Agency

e - Outcome Evaluation

FDA- Food and Drug Administration

FP - Family Physician

FSMB – Federation of State Medical Boards

GP - General Practitioner

PBC - Perceived Behavioral Control

PCP - Primary Care Physician

PNS - Peripheral Nervous System

RPB - Recent Past Behavior

SN - Subjective Norm (also known as social norm)

TAFP - Texas Academy of Family Physicians

TMB - Texas Medical Board

TPB - Theory of Planned Behavior

TRA - Theory of Reasoned Action

CHAPTER 1: INTRODUCTION

"Pain is perfect misery, the worst of evils, and excessive, overturns all patience."

- John Milton, *Paradise Lost*

1.1 Background

The adequate treatment of chronic non-malignant pain (CNMP) continues to be a major public health concern. It is estimated that close to one-third of the industrialized world population suffers from some type of chronic pain (Loesser, 1999). The American Pain Society (APS) (2000) estimates that nine percent of the U.S. population suffers from moderate to severe CNMP. Of these sufferers, many individuals have been living with their pain virtually on a daily basis for more than five years. CNMP is considered a pervasive and costly health care problem. Seen by experts as a leading reason why patients seek medical care in developed countries, the adequate management of CNMP is considered an important problem in both primary care and out-patient medicine (Zagari *et al.*, 1996; Loesser, 1999). The intrinsic sensory, emotional and behavioral components associated with the etiology and severity of CNMP often makes treatment of this type of pain complex. Fortunately, a number of therapeutic alternatives are available to treat chronic pain. The use of opioid analgesics is one treatment option that is considered to have an important role in this type of pain management.

Advancements in pharmacotherapeutics have produced a number of medications created to assist physicians in managing their patients' chronic pain. Opiate analgesics (schedule II – IV), which until 30 to 40 years ago were primarily confined to hospital and inpatient settings, are becoming widely used to treat various levels of chronic pain in the outpatient setting (Anesthetic and Life Support Drugs Advisory Committee, 2003). The use of "long-acting" or controlled-release opioids (CR opioids) is one treatment option that has achieved wide-spread acceptance among health practitioners in its role to treat pain in cancer and terminally-ill patients. However, the use of this class of analgesics to manage moderate to severe CNMP is somewhat controversial (Goli& Finley, 2005).

The controversy over the use of CR opioids to treat patients in pain has been extensively discussed in the lay press and scientific literature. Empirical evidence has shown CR opioids to be an effective tool in treating patients suffering from moderate to severe CNMP, especially among patients who require sustained analgesia (Simpson *et al.*, 1997; Allan *et al.*, 2001; Glajchen, 2001; Washington State Department of Labor and Industries, 2002; Davis *et al.*, 2003; Lauretti *et al.*, 2003; Fisher, 2004a). In fact, many of the more recently published pain management guidelines and evidenced-based studies recommend the use of "long-acting" opioids to treat a specific group of patients suffering from moderate to severe CNMP (Gardner-Nix, 2003). However, the use of CR opioids to treat this type of pain has not been widely accepted among many practitioners (Gureje *et al.*, 1998; American Pain Society, 2000; AMA, 2004). Previous research suggests that some physicians are reluctant to prescribe CR opioids to CNMP patients that may benefit from its long-acting analgesic properties. In fact, some physicians are reluctant or unwilling to prescribe CR opioids to treat CNMP patients, even when it is medically appropriate (Turk *et al.*, 1994; Turk, 1996; Potter *et al.*, 2001; Gourlay *et al.*, 2004; Clark, 2005). Concerns of patient addiction, physical dependence, illicit usage, and fear of regulatory scrutiny are some of the factors that may affect physicians' willingness to prescribe CR opioids (Glajchen, 2001; Gardner-Nix, 2003). Consequentially, these physician-related barriers may result in CNMP patients receiving inadequate treatment for their pain.

Primary care physicians (PCPs) play a critical role in the management of chronic pain among a diverse group of patients. PCPs see more patients than any other specialty (U.S. Department of Health and Human Services, 2005). They are also considered to be on the front-line in providing treatment to patients seeking pain relief. As a result, the successful management of CNMP patients is dependent on the ability of PCPs to understand and utilize effective pain management therapies including the use of CR opioids.

Experts agree that many physician-related barriers hinder the delivery of adequate pain management to patients with CNMP (Gilson& Joranson, 2001). But, what causes physicians to under treat pain? In addition, what underlying factors could influence physicians' decisions to use CR opioid analgesics for patients with CNMP? Numerous studies have attempted to examine the knowledge and beliefs of physicians to better understand the reasoning underlying their treatment behaviors (Weissman *et al.*, 1991; Turk *et al.*, 1994; Polit& Hungler, 1995; Turk, 1996; Weinstein *et al.*, 2000, 2000a; Potter *et al.*, 2001). However, little is known about primary care physicians' attitudes or willingness to prescribe CR opioids to patients suffering from moderate to severe CNMP.

Attitudes toward CR opioids and their role in treating pain may affect physicians' decisions to prescribe this type of analgesic for CNMP. In addition to their own attitudes, physicians may consider the beliefs of other individuals and groups (e.g., patients, colleagues, staff, family, medical boards) in their decision-making to prescribe this type of opioid analgesic. Further, the level of control physicians have in their prescribing decisions may be influenced by external factors such as formularies, regulatory policies, or utilization management strategies. As a result, it is suspected that the above mentioned factors play some role in the formation of physicians' intentions (i.e., willingness) to prescribe CR opioids for CNMP.

The proposed study will examine some of the issues affecting the use of CR opioids in pain management. In particular, it will identify and explore factors that are believed to influence physicians' willingness to prescribe CR opioids.

1.2 Statement of Purpose

The purpose of this study is to use the Theory of Planned Behavior (TPB) model to identify and examine factors affecting family physicians (FPs) attitudes and beliefs toward the use of CR opioids to treat patients with moderate to severe CNMP. Further, the study will explore the predictive utility of the TPB in understanding FPs willingness to prescribe CR opioids to treat patients with moderate to severe CNMP.

1.3 Statement of Problem

Primary care physicians (PCPs) play a critical role in the management of chronic pain among a diverse group of patients. Though management of severe chronic pain will likely continue to be handled by pain specialists, PCPs are beginning to take on an increased responsibility for managing patients suffering from moderate to severe CNMP. Many therapeutic alternatives are available to physicians when it comes to treating CNMP patients. One treatment modality that is gradually gaining acceptance is the use of CR opioid analgesics (Davis *et al.*, 2003). Recently published pain management guidelines recommend the use of CR opioids to treat a specific group of patients suffering from moderate to severe CNMP (Gardner-Nix, 2003). However, some physicians are reluctant to prescribe CR opioids to CNMP patients, even when it is medically appropriate. Physicians' beliefs regarding the use of CR opioids for CNMP and educational deficiencies in pain management are believed to create barriers that lead to ineffective pain management. Consequentially, their reluctance in prescribing CR opioids may result in the unnecessary suffering of their CNMP patients.

Little research has been conducted to investigate what factors influence physicians' attitudes toward prescribing CR opioids. In addition, little is known about PCPs' willingness to prescribe CR opioids to patients suffering from moderate to severe CNMP. Therefore, a need exists to identify and examine factors that influence physicians' willingness to prescribe CR opioids for moderate to severe CNMP. A study of this type will increase our understanding of physicians' intentions and behaviors in prescribing CR opioids to CNMP patients.

1.4 Significance of Objectives

The significance of the proposed study is that, through the use of the Theory of Planned Behavior (TPB), investigators may be able to identify and better understand those factors (i.e., attitudes, social norms, and behavioral control beliefs) that influence family physicians' willingness to prescribe CR opioids to patients with moderate to severe CNMP. Study findings could provide insight into behavioral concepts influencing physician CNMP treatment decisions. This information would be valuable to the initiatives of health care practitioners, public health officials, regulatory agencies and continuing educational programs. As a result, this information could be used to better meet the educational needs of primary care providers and ultimately the needs of their CNMP patients and the community.

1.5 Overview of Dissertation

A review of the literature on CNMP, CR opioid analgesics, physician pain management practices, and physician attitudes and views toward prescribing opioid analgesics was conducted to identify and examine areas perceived to affect physicians' willingness to prescribe long-acting opiate analgesics to patients diagnosed with moderate to severe CNMP. The Theory of Planned Behavior (TPB) was utilized to examine family physicians' willingness (intention) to prescribe CR opioids. The constructs of the model were used to assess family physicians' attitudes, subjective norms and perceived behavioral control toward the use of CR opioids to treat CNMP. In Chapter 2, an overview of the etiology and impact of CNMP is discussed, a review of opioid analgesics used to treat chronic pain is provided, and a review of the literature of physician beliefs toward the use of opioids to treat CNMP is presented. In Chapter 3, the research model, Theory of Planned Behavior, and the constructs associated with the model is discussed. In Chapter 4, the research methodology is presented. In Chapter 5, study results are presented and Chapter 6 provides a discussion of the results, limitations, and conclusions of the research study.

CHAPTER 2: LITERATURE REVIEW

"Chronic pain is one of the most pervasive and costly health care problems today" (Zagari *et al.*, 1996). Seen by experts as the leading reason why patients seek medical care in developed countries, the adequate management of chronic pain is considered an important problem in both primary care and outpatient medicine (Zagari *et al.*, 1996; Loesser, 1999). Numerous therapeutic options have become available to treat individuals suffering from moderate to severe chronic pain. The use of controlled-release opioids (CR opioids) is one treatment option that has achieved wide-spread acceptance among health practitioners in its role to treat chronic malignant pain. However, the use of this class of analgesics to manage chronic non-malignant pain (CNMP) is somewhat controversial (Goli& Finley, 2005).

A lack of consensus exists among physicians and other health practitioners on how and when to prescribe this class of opioid analgesics to patients suffering from CNMP (Dickinson *et al.*, 2000). Physicians' beliefs toward the use of CR opioids for CNMP and deficiencies in education in pain management are believed to create barriers that lead to ineffective pain management. As a result, a substantial number of physicians continue to under treat patients suffering from moderate to severe CNMP (American Pain Society, 2000). This chapter provides an overview of CNMP and the therapeutic options used to treat the condition. It will examine the economic and epidemiological impact of CNMP and review CR opioid analgesics. The latter half of the chapter will examine the role of family physicians in pain management and barriers to prescribing CR opioids.

2.1 Chronic Non-Malignant Pain (CNMP)

Types of Pain

CNMP is considered a complex disorder with a myriad of intrinsic sensory, emotional, and behavioral components contributing to its etiology and severity (McCarberg, 2004). Left untreated or under treated, CNMP can have a substantial negative impact on an individual's quality of life. It may affect a person's ability to concentrate, function at work, exercise, socialize, participate in leisure time activities, or even attain proper rest. The impact of CNMP can also be emotionally detrimental. Individuals suffering from unrelieved chronic pain are at increased risk of depression, anxiety, or other psychological conditions that may manifest as a result of uncontrolled pain (American Pain Society, 2000).

Numerous definitions have been created to describe pain. The International Association for the Study of Pain (IASP) describes it as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage" (Merskey& Bogduk, 1994). Pain is often considered a subjective experience. Many clinicians see pain as being so subjective in meaning that they often define pain as "whatever the patient says it is" (Baumann, 2002).

Pain can arise from a myriad of physiologic pathways depending on the type of injury experienced by the patient. Other definitions have been established to describe specific types of pain as it relates to its origin, severity, and duration (McPherson *et al.*, 2004). The IASP developed a list of standardized pain terms for use by physicians in clinical practice. Table 2.1 provides a list of several commonly used chronic pain terms.

Table 2.1 IASP[1] Chronic Pain Terms

Term	Meaning
Allodynia	Pain due to a stimulus that does not normally provoke pain.
Analgesia	Absence of pain in response to stimulation which would normally be painful.
Causalgia	Persistent burning pain, allodynia, and hyperpathia following traumatic nerve lesion.
Central pain	Pain initiated or caused by a primary lesion or dysfunction in the central nervous system.
Dysesthesia	An unpleasant abnormal sensation, whether spontaneous or evoked.
Hyperalgesia	An increased response to a stimulus which is normally painful.
Hyperpathia	Abnormally painful reaction to a stimulus, especially a repetitive stimulus, as well as an increased threshold.
Hypoalgesia	Diminished pain in response to a normally painful stimulus.
Neuralgia	Pain in the distribution of a nerve or nerves.
Neuritis	Inflammation of a nerve or nerves.
Neuropathic pain	Pain initiated or caused by a primary lesion or dysfunction in the nervous system.
Paresthesia	An abnormal sensation, whether spontaneous or evoked.

[1.] IASP = International Association for the Study of Pain

Source: Adapted from (Merskey& Bogduk, 1994)

2.1.1 Pathophysiology of Pain

Pain arises from a variety of causes and is classified on the basis of the presumed underlying pathophysiology. A number of models have proposed mechanisms that explain pain as it affects individuals. The gate control theory (GCT), proposed by Melzack and Wall in 1965, is considered one of the more generally accepted models used to explain the perception of pain. According to the GCT, pain perception is attributed to mechanical and psychological stimuli. Further, pain is considered not only to involve sensory perceptions, but also affective and cognitive dimensions (Melzack& Wall, 1965).

Typically associated with tissue damage, pain is considered a primary indicator of physiological trauma. However, pain does not always have a direct correlation to an identifiable cause of injury. The perception of pain commonly develops from a system of sensory neurons (i.e., nociceptors) and neural afferent pathways that are responding to potentially noxious tissue-damaging stimuli. Conversely, non-nociceptive pathophysiologic causes (e.g., abnormal nervous system processing or psychological factors) can influence nociception (Besson& Chaouch, 1987; Turk& Okifuji, 2000; Baumann, 2002; Evans *et al.*, 2003d).

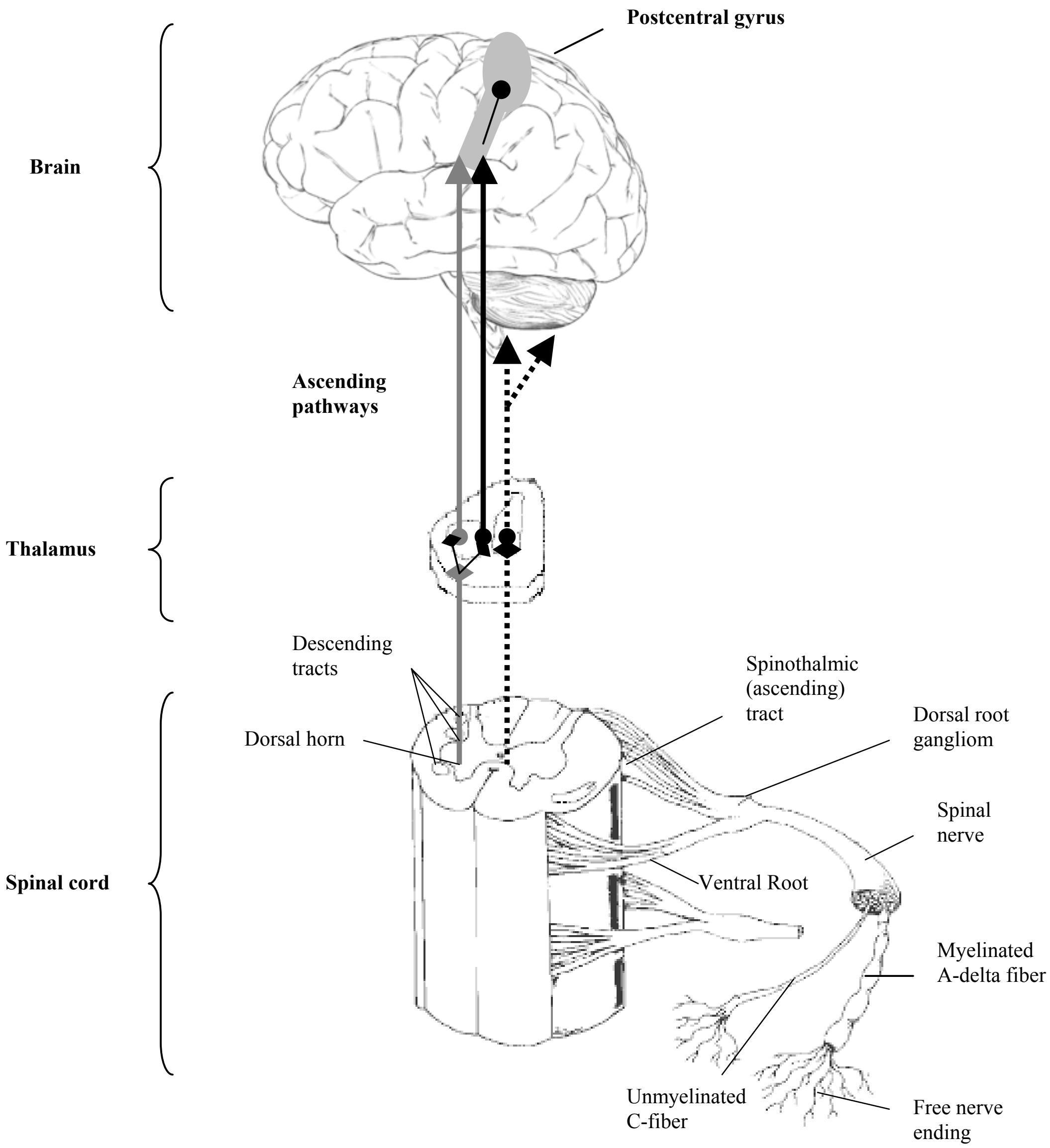
According to the American Medical Association (2003a), the pathophysiology of pain can be divided into one of three categories: (1) nociceptive, (2) neuropathic, and (3) idiopathic. The processes and the interrelationships of the various underlying mechanisms that are believed to cause each of the categories of pain are highly complex (McCarberg, 2004). A brief overview of each of the categories will discuss how each of these factors work together to produce the pain response. A more in-depth explanation of the pain process is provided by Besson and Chaouch (1987).

Nociceptive Pain

The first category of pain is nociceptive pain which involves the normal activation of the nociceptive system by noxious stimuli (Evans *et al.*, 2003d). Nociceptive pain occurs subsequent to tissue damage and is commonly associated with superficial somatic, deep somatic, and visceral pain syndromes. The severity of this type of pain is related to the degree of receptor stimulation (as related to the degree of injury) transmitted by nerve fibers to the central nervous system (CNS) (American Pain Society, 2000; Baumann, 2002).

Generally, normal processing of nociceptive stimuli involves the interaction of primary and afferent pain modulating systems. Normal processing of painful stimuli is transmitted via nociceptors (A-delta nerve and C-fibers) to the CNS (Figure 2.1). Signal processing continues in the dorsal horn of the spinal cord, ascending neural pathways, thalamic and other specialized brain structures.

Figure 2.1 **Pathophysiology of Nociceptive Pain**



Source: Adapted from (Evans et al., 2003d; McPherson et al., 2004)

Examples of nociceptive pain include: (1) trauma of the skin, subcutaneous tissue, or mucous membranes; (2) deep somatic pain of the muscle, tendons and bones which commonly occurs in individuals suffering from arthritis pain, or tendonitis; and (3) visceral pain including colic, appendicitis, pancreatitis, peptic ulcer or bladder distension.

Conceptually, pain of this type can be thought of as being composed of three hierarchical levels: a sensory-discriminatory component, a motivational-affective component, and a cognitive-evaluative component (Evans *et al.*, 2003d). Researchers are not completely clear on how the body perceives this information as being painful, but this type of pain arises from inflammation of tissue caused from stimulus of nociceptor sensory receptors reacting to acute tissue trauma or prolonged damage to tissue (McCarberg, 2004).

Most nociceptive pain disorders are temporary conditions and may or may not require the use of medications to reduce inflammation and relieve pain. These disorders resolve when inflammation of the tissue is removed or treated (American Pain Society, 2000; McCarberg, 2004). Patients experiencing nociceptive pain describe it as stimuli that is sharp, dull, aching or throbbing in nature (McCarberg, 2004). Nociceptive pain processes can be associated with both acute and chronic pain. For example, inflammation may result from the stimulation of both inflammatory cells and nociceptors caused by acute tissue trauma. In addition, chronic inflammation with nociceptive stimulation may be the source of persistent pain. Further, secondary neural changes that lead to chronic nociceptive pain may also be caused by tissue injury (McCarberg, 2004).

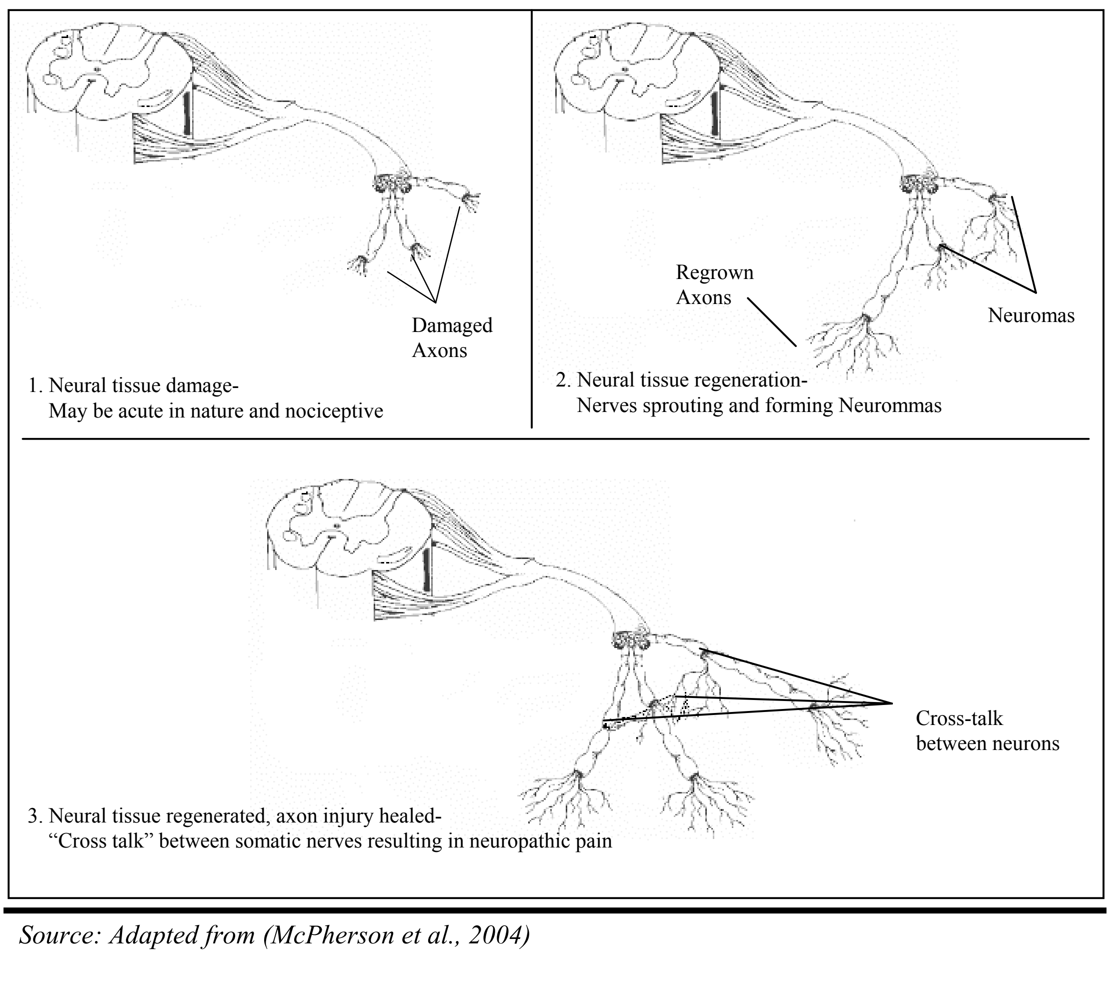
Neuropathic Pain

Neuropathic pain is the second pain syndrome category that arises from pathophysiologic changes in the CNS or peripheral nervous systems (PNS). Generally, these changes may stem from injury to the neural or non-neural tissues (Evans *et al.*, 2003d). Neuropathic pain may originally stem from disease, nervous system injury or impairment which leads to irregular signal processing of the PNS and CNS. This pain syndrome may be a result of nerve injury, secondary to tissue damage. Meaning, this type of pain becomes independent of the initial injury or damage, resulting in a sustained chronic pain state (American Pain Society, 2000; Dickinson *et al.*, 2000; Baumann, 2002; Evans *et al.*, 2003d; McCarberg, 2004).

Neuropathic pain can be referred to as “pathologic pain” because it serves “no purpose” (Baumann, 2002). Unlike nociceptive pain, which arises from pain due to inflammatory processes, neuropathic pain is generally caused by a primary lesion or nerve dysfunction. The pathophysiological process of neuropathic pain is not completely understood due to this type of pain arising in the absence of obvious tissue damage. However, research has shown that this pain syndrome may be associated with referred pain, allodynia (i.e., pain induced by light touch), hyperalgesia (i.e., increased response to noxious stimuli), or hyperpathia (i.e., exaggerated responses to painful stimuli, with continuing sensation of pain after the stimulation has ceased) (Baumann, 2002; Burke& Weitz, 2002; Evans *et al.*, 2003d; Argoff *et al.*, 2005).

Researchers hypothesize that neuropathic pain arises from neurophysiologic and neuroanatomic changes that occur following injury to neural tissue (Evans *et al.*, 2003d). Abnormal nerve regenerations can occur as a result of injury to peripheral neural axons (Figure 2.2).

Figure 2.2 **Neuropathic Pain: Regeneration of Damaged Neural Tissue**



Source: Adapted from (McPherson et al., 2004)

Damaged axons may grow multiple nerve sprouts (e.g., neuromas) which can generate spontaneous activity, allowing pain pathways to be more sensitive to physical distention. Atypical neural connections may develop between damaged nerves (e.g., nerve sprouts or demyelinated axons) allowing "cross-talk" to occur between somatic nerves, sympathetic efferent nerves and nociceptors. In addition, dorsal root fibers may also sprout following injury to peripheral nerves. This rewiring process can produce persistent nerve or neuronal pain stimulation weeks or months after healing has occurred (Baumann, 2002; Evans *et al.*, 2003d; Argoff *et al.*, 2005).

Neuropathic pain is often described as a burning, tingling, or electrical sensation (McPherson *et al.*, 2004). Examples of neuropathic pain include: spinal cord injury, post-stroke pain, HIV myelopathy, diabetic neuropathy, plexus avulsion injury, post-herpetic neuralgia, trigeminal neuralgia, peripheral nerve injury, carpal tunnel syndrome, post-mastectomy pain, and pain associated with some cancers (American Pain Society, 2000; Baumann, 2002; Burke& Weitz, 2002; Argoff *et al.*, 2005).

Idiopathic Pain

The third pain category is idiopathic pain. Also known as psychogenic pain, idiopathic pain is a syndrome that occurs spontaneously and is not associated with any known cause. Idiopathic pain lacks a demonstrable organic cause and is attributed to a high prevalence of anxiety and depression experienced among patients (Burton, 2005). Conditions included in this pain syndrome include idiopathic facial pain and atypical odontalgia (European Association of Oral Medicine, 2005).

Psychological factors can contribute to idiopathic pain severity. The psychological state of an individual experiencing this type of pain can have a major impact on their perceived severity of pain, the subjective nature of pain, and how well it is accepted (Evans *et al.*, 2003d). Idiopathic pain often accompanies anxiety, depression, and other affective or psychological disorders, which may contribute to the physiological symptoms associated with both nociceptive and neuropathic pain (Evans *et al.*, 2003d). As a result, the ability to identify and assess idiopathic or “psychogenic” pain is considered essential when assessing pain syndromes.

Other Pain

Another type of pain not included in the previously discussed categories is "mixed" or "unspecified" pain. This type of pain can be a result of a combination of nociceptive and neuropathic pain. Examples of mixed pain syndrome include chronic recurrent headaches and vasculopathic pain (Burke& Weitz, 2002). Treatment of mixed nociceptive or neuropathic chronic pain is considered rarely effective in completely eliminating pain. As a result, the pain management goals associated with this condition are primarily focused in the improvement of quality of life (McCarberg, 2004).

2.1.2 Classification of Pain

Several classification systems have been developed to describe the forms of pain (McPherson *et al.*, 2004), most of which divide pain syndromes into three groups: acute, persistent or chronic, and malignant pain (Ashburn& Staats, 1999; American Pain Society, 2000; Evans *et al.*, 2003b; McPherson *et al.*, 2004). These classifications encompass a wide variety of pain syndromes. The American Pain Society classifies the division as (1) acute pain, (2) chronic malignant pain, and (3) chronic non-malignant pain.

Although there are many distinctions between the categories, the fundamental differences relate to the duration of pain, its etiology, and its prognosis (Table 2.2) (McPherson *et al.*, 2004). The ability to distinguish between acute and chronic pain is particularly relevant in the selection of analgesia. Once pain becomes chronic, specific treatment strategies must be changed to manage it (Evans *et al.*, 2003d).

Table 2.2 Classifications of Pain: Acute and Chronic Pain

Characteristic	Acute Pain	Chronic Non-Malignant Pain	Chronic Malignant Pain[1]
Duration	Hours to weeks, depending on cause	Months to years	Unpredictable
Pathology	Present	Often little or none	Usually present
Examples of causes	Tissue injury, surgery, medical procedures, and other trauma.	Ongoing tissue injury (e.g., arthritis), back pain (with or without associated pathology), headache	Cancer or cancer treatments, acquired immunodeficiency syndrome, congestive heart failure, multiple sclerosis
Prognosis	Predictable	Unpredictable	Increasing pain with the possibility of disfigurement or death
Complicating issues and psychosocial effects	Uncommon	Profound complications including depression, anxiety, and financial issues	Usually profound, including loss of control, issues of confronting one's mortality
Nerve conduction	Rapid	Slow	Slow
Autonomic nervous system involvement	Present	Generally absent	Present or absent
Biologic value	High	Low or absent	Low
Treatment	Primarily analgesics	Multimodal	Multimodal

[1.] Defined as pain resulting from any progressive, potentially life-threatening disease.
Source: (Ashburn& Lipman, 2004)

Acute pain

According to Chapman and Nakamura (1999), acute pain is described as "a complex, unpleasant experience with emotional and cognitive, as well as sensory features that occur in response to tissue trauma" (Chapman& Nakamura, 1999). Acute pain characteristically manifests following an injury, surgery or tissue trauma. This form of pain is generally nociceptive in nature and serves as a biological defense mechanism that warns the sufferer of tissue damage or the potential for further injury (Baumann, 2002; McPherson *et al.*, 2004).

The etiology of acute pain is typically described to have recent onset having a short duration, usually lasting no more than a few days or weeks (Evans *et al.*, 2003d). Acute pain can be seen as an adaptive beneficial response needed for the preservation of tissue integrity. The key characteristic of this type of pain is that it generally subsides as healing occurs and pain producing stimuli remits with the resolution of injury (American Pain Society, 2000; Brennan& Heit, 2005).

Chronic Pain

The second and third categories of pain are chronic malignant and chronic non-malignant pain. Chapman and Stillman (1996) generally describe chronic pain as pain that extends beyond the period of healing, usually beyond three to six months. This type of pain often does not relate directly to injury or provide physiologic value but instead is considered as pain that has outlived its usefulness (Chapman& Stillman, 1996; American Pain Society, 2000; Edwards *et al.*, 2001; Potter *et al.*, 2001; McPherson *et al.*, 2004).

The etiology of chronic pain is not well-understood. Unlike acute pain, chronic pain can persist for months or years and is generally considered neuropathic (McCarberg, 2004; Goli& Finley, 2005). The pathology associated with this type of pain is not clearly defined which makes it difficult to diagnose and treat (Chapman& Stillman, 1996). This type of pain can be caused from persistent stimulation of nociceptors, specifically in the area of ongoing tissue damage (e.g., osteoarthritis). Frequently, however, chronic pain perpetuates from factors that are remote to the cause or damage, long after trauma has occurred (Ashburn& Staats, 1999). Chronic pain can lead to poor physical functioning, depression, irritability, social withdrawal, vegetative like symptoms, disruption of work and interference of social relationships (American Pain Society, 2000; Gerstle *et al.*, 2001; Baumann, 2002; McCarberg, 2004; McPherson *et al.*, 2004).

Chronic Malignant Pain

Chronic malignant pain is traditionally described as pain arising from either tumors or treatments such as chemotherapy, radiation or surgery (Ashburn& Staats, 1999). More recent definitions have expanded chronic malignant pain to include pain associated with a progressive disease that is potentially life limiting, resulting from conditions such as acquired immunodeficiency syndrome (AIDS), progressive neurological diseases, end-stage organ failure, and dementia (Ashburn& Lipman, 2004).

Chronic Non-Malignant Pain

Chronic non-malignant pain (CNMP) is traditionally described as "pain that has lasted three to six months or longer, is ongoing, due to non-life-threatening causes, has not responded to current available treatment methods and can continue for the remainder of the patient's life" (Dunajcik, 1999). A more recent definition, however, describes CNMP as "pain persisting for at least one month beyond the usual course of an acute illness, or the time required for an injury to heal; or pain associated with a persistent pathologic process; or pain recurring at intervals of months or years" (Evans *et al.*, 2003b).

The etiology of CNMP is not well understood. Further, CNMP pain syndromes frequently have poorly understood organic causes and less well-defined patterns (Dunajcik, 1999). The American Pain Society (2000), describes CNMP as pain resulting from a persistent debilitating condition that may result in significant physical, emotional and social disabilities. Consequentially, CNMP can be difficult to diagnose if it develops in the absence of a defined injury or disease process (Dunajcik, 1999; American Pain Society, 2000). CNMP is often mulitfactorial in origin and may originate from acute injuries that ultimately lead to chronic pain conditions. It often cannot be explained by objective clinical measures alone and its cause may be idiopathic in nature. The severity of this type of pain condition can range from mild to severe and may affect any region of the body (Woolf, 1993; Baumann, 2002).

According to the American Pain Society (2000), CNMP is considered a non-life-threatening condition or illness (American Pain Society, 2000). Examples of this type of chronic pain included chronic lower back pain, osteoarthritis and other types of musculoskeletal conditions (Gerstle *et al.*, 2001). Depending on its severity, CNMP can affect the daily lives of its sufferers and may result in vocational, interpersonal, and/or psychological problems.

Patients experiencing CNMP may develop a psychological disorder known as chronic pain syndrome (CPS). Patients with persistent pain who exhibit two of the following characteristics are classified as having CPS: (1) report persistent pain lasting longer than three months–with or without physical causes, (2) demonstrate progressive deterioration in their ability to function at home, socially or in the work place, (3) experience increased health care utilization (e.g., repeated physical evaluations, diagnostic tests, request for pain medications or invasive medical procedures), (4) demonstrate mood disturbance, and (5) exhibit clinically significant anger and hostility (Sanders *et al.*, 1999). Though not all CNMP patients develop this syndrome, the pain experienced by this group is real (Dunajcik, 1999). As a result, "appropriate management of both CNMP and CPS requires an interdisciplinary approach that addresses the complex interaction of physical, psychological, and social factors that contribute to the ongoing pain" (American Pain Society, 2000).

2.2 Epidemiology and Economics of CNMP

Epidemiology

Previous studies have estimated the prevalence of chronic pain to be between two and 45 percent of the world's population (Crook *et al.*, 1986; Brattberg *et al.*, 1989a; Magni *et al.*, 1993; Gureje *et al.*, 1998; Verhaak *et al.*, 1998). This variability in prevalence may be attributed to the heterogeneity in definitions used to describe chronic pain, types of populations studied, and survey methodologies used to conduct the study.

Among industrialized nations, chronic pain is projected to affect one-third of the populace with almost half of sufferers experiencing some level of disability resulting from their pain (Table 2.3) (Verhaak *et al.*, 1998; Loesser, 1999). The prevalence of chronic pain within the U.S. is estimated to be between 12 and 26 percent of the population, or somewhere between 35 to 75 million people (Schnitzer, 1998; American Pain Society, 2000; Parrott, 2002).

Table 2.3 Prevalence of Chronic Pain: Results of International Studies Conducted Between 1984 to 1994

Authors	Country	Prevalence	Survey method	Definition of chronic	Non-response
(Potter& Jones, 1992)	England	< 1%[a]	GP[b]	>6 months	n.a.
(Kohlmann, 1991)	Germany	2%	Postal	>1 month	20%
(Bowsher *et al.*, 1991)	Great Britain	7%	Telephone	>3 months	--[c]
(VonKorff *et al.*, 1988; VonKorff *et al.*, 1990, 1993)	USA	8%	Postal	"Persistent"	20%
(Frelund& Frelund, 1986)	Denmark	9%	GP[b]	>3months	n.a.
(Crook *et al.*, 1984)	Canada	11%	Telephone	>2 weeks (Persistent)	5%
(Croft *et al.*, 1993)	England	13%	Postal	>3 months	34%
(Magni *et al.*, 1990, 1992)[d]	USA	14% - 20%	Survey	>1 month	--[c]
(Andersson *et al.*, 1993; Andersson, 1994)	Sweden	18%	Postal	>3 months	15%
(Sternbach, 1986)	USA	10 - 29%	Telephone	>3 months	--[c]
(Ma¨ke´la¨& Helio¨vaara, 1991)	Finland	17 - 45%	Clinical examination	--[c]	10%
(Andersen& Worm-Pedersen, 1987)	Denmark	30%	Postal	--[c]	10%
(Brattberg *et al.*, 1989b)	Sweden	40%	Postal	>6 months	33%
(James *et al.*, 1991)	New Zealand	82%[e]	Survey	No time limit	30%

[a] Incidence, not the prevalence
[b] General practitioner
[c] No data given
[d] Musculoskeletal and abdominal pain
[e] Life-time prevalence
Source: adapted from (Verhaak et al., 1998) Table summary

Prevalence of CNMP

CNMP is seen as a significant problem throughout the industrialized world, with a prevalence of 10 to 55 percent, depending on the definition used to characterize the disorder (Novak *et al.*, 2004). Results from a 1992 World Health Organization (WHO) survey conducted on 5,438 primary care patients located in 15 countries throughout Asia, Africa, Europe and the Americas, found that persistent pain was a commonly reported health problem among primary care patients (Gureje *et al.*, 1998). The international study found 40 percent of respondents living in industrialized countries experienced some level of CNMP due to arthritic or muscoskelatal disorders. Back pain, headache, and joint pain were the most common types of pain reported. Of the patients who were admitted to primary care facilities, 22 percent (n=1196) reported having experienced persistent pain lasting longer than six months (Gureje *et al.*, 1998).

The American Pain Society (2000) estimates that nine percent of the U.S. population suffers from moderate to severe CNMP. A 1988 U.S. National Health Interview Survey (NHIS) found chronic daily back pain to be the most prevalent impairment in individuals 65 years and older. According to the survey, this form of back pain was responsible for more disability than cancer, heart disease, stroke and AIDS combined among individuals 18 to 55 years of age (Praemer *et al.*, 1992; Stoddard *et al.*, 1998; Loesser, 1999). Approximately 55 percent of Americans aged 65 and over experience pain on a daily basis. Results from a 1999 U.S. Gallup survey found that 42 percent of adults–approximately 80 million people–experienced some level of pain every day. Of those experiencing pain, fewer than half (43%) reported that they had a "great deal of control" over their pain. In addition, 28 percent believed that there was no solution to their pain (Arthritis Foundation, 2003).

Data from a 1998 U.S. National Institute on Disability and Rehabilitation Research report indicated that 22.7 million people aged 18 to 69 had some level of work limitation directly resulting from chronic pain (Stoddard *et al.*, 1998). Findings from the 1999 "National Pain Survey" show that 24 percent (48 million) of Americans live with some type of chronic pain which lasted for six months or longer (Ortho-McNeil Pharmaceutical, 1999; American Pain Society, 2000; Weiner, 2001). Of these individuals, 20 million experienced such severe pain that they were unable to work and 30 million were unable to engage in daily routine activities. A 2000 report published by the Joint Commission on Accreditation of Healthcare Organization (JCAHO) found that on average 50 million Americans are either partially or totally disabled due to pain each year (JCAHO, 2000). The economic impact associated with this group of pain sufferers will be discussed in the next section.

Economics

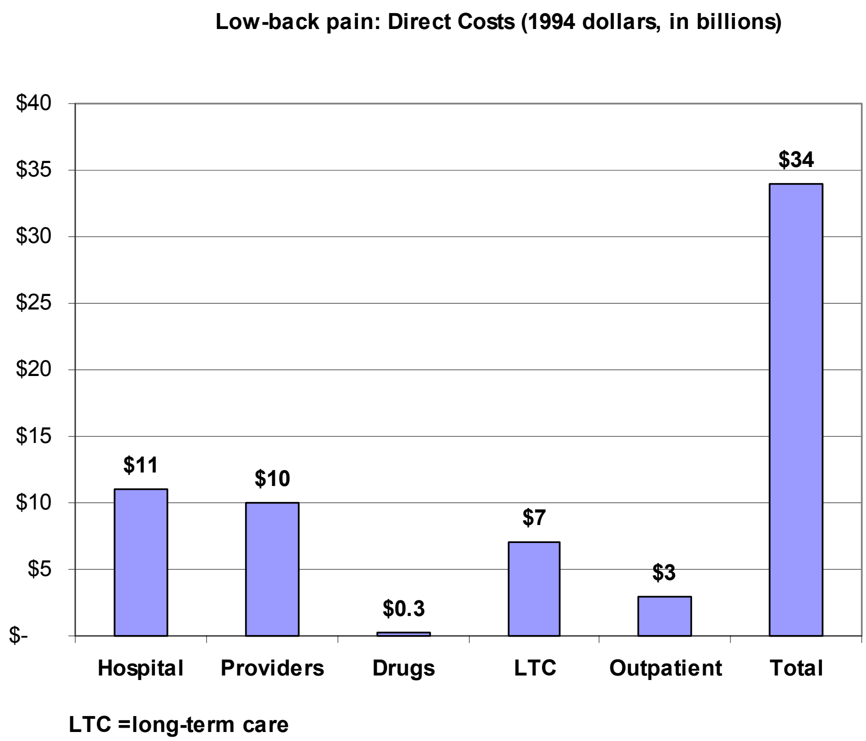
The total annual cost associated with treating chronic pain in the U.S. is estimated to be in the billions of dollars. Few studies, however, have been able to accurately assess the true direct and indirect costs of CNMP (Grichnik& Ferrante, 1991; Praemer *et al.*, 1992; Andersson, 1999; Gallagher, 1999; Schnitzer *et al.*, 2000; Thomsen *et al.*, 2001; Breen, 2002). National economic data available for CNMP is particularly sparse especially for the utilization of health care services, drug utilization and, changes in work and occupational status as related to productivity (Thomsen *et al.*, 2001). In addition, there is limited comprehensive data that incorporates the costs of treating co-morbid conditions that may develop from or become exacerbated as a result of chronic pain.

Annual economic costs associated with chronic pain appear to be increasing over the past several decades. A 1983 study conducted by Anronoff *et al.* (1983) estimated the annual economic costs associated with treating chronic pain in the U.S. to be $US40 billion a year. By 1991, that number had grown to $US65 billion (Grichnik& Ferrante, 1991). A study published in 2000 estimated the costs to be as high as $US100 billion per year (Schnitzer *et al.*, 2000).

Hospital charges and physician-related expenses comprise a substantial portion of the costs related to chronic pain treatment (Von Korff *et al.*, 1991). A United Kingdom study estimated the direct costs of treating chronic back pain to be £UK1.6 billion, of which physiotherapy and hospital utilization accounted for the majority of costs. Indirect costs (e.g., time lost from work and caregiver time) of back pain in the British health system was estimated to be £UK5 billion annually (Maniadakis& Gray, 2000). A 1989 New Zealand study found that physician-related expenses were higher among chronic pain patients. In the study, patients reported seeing their general practitioner 12.9 times a year compared with 4.2 visits in the general population (James& Large, 1992).

In the U.S., low-back pain and osteoarthritis are considered significant drivers of both inpatient and outpatient health care utilization (Emons, 2003). Total U.S. direct costs associated with lower back pain in 1994 was estimated to be $US34 billion with approximately $US11 billion related to hospital charges and $US300 million from drug costs (Lee, 1994; Emons, 2003). Figure 2.3 illustrates a breakdown of direct health costs in the long-term care of chronic lower back pain (Frymoyer, 1997).

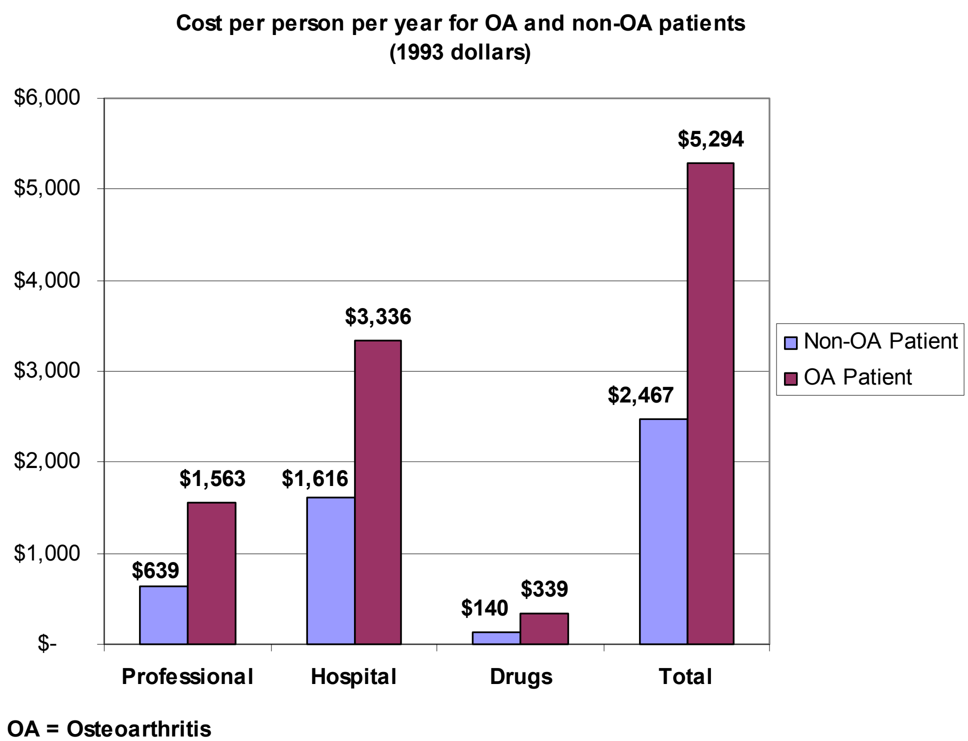
Figure 2.3 **Annual U.S. Direct Health Care Costs of Chronic Lower Back Pain**



Source: (Frymoyer, 1997)

A 1998 MacLean *et al*. retrospective cohort study conducted among a managed care population in the U.S. found the total costs for treating patients with persistent osteoarthritic pain under the age of 65 to be $US5,294 per patient per year (in 1993 dollars). This cost was seen to be more than twice that for age-matched non-osteoarthritic patients (Figure 2.4). Approximately 61 percent of the cost differential was attributed to inpatient hospital costs. Osteoarthritis was also seen to be a substantial component of indirect and nondirect medical costs (i.e., indirect costs- work absenteeism, lost productivity, disability; and nondirect costs- transportation, custodial care, and child care). Total indirect and nondirect costs were US$726 per person per year (in 1993 dollars), compared to US$335 for nonosteoarthritic patients (MacLean *et al.*, 1998).

Figure 2.4 **Annual Treatment Costs of Chronic Osteoarthritic Pain within the U.S.**



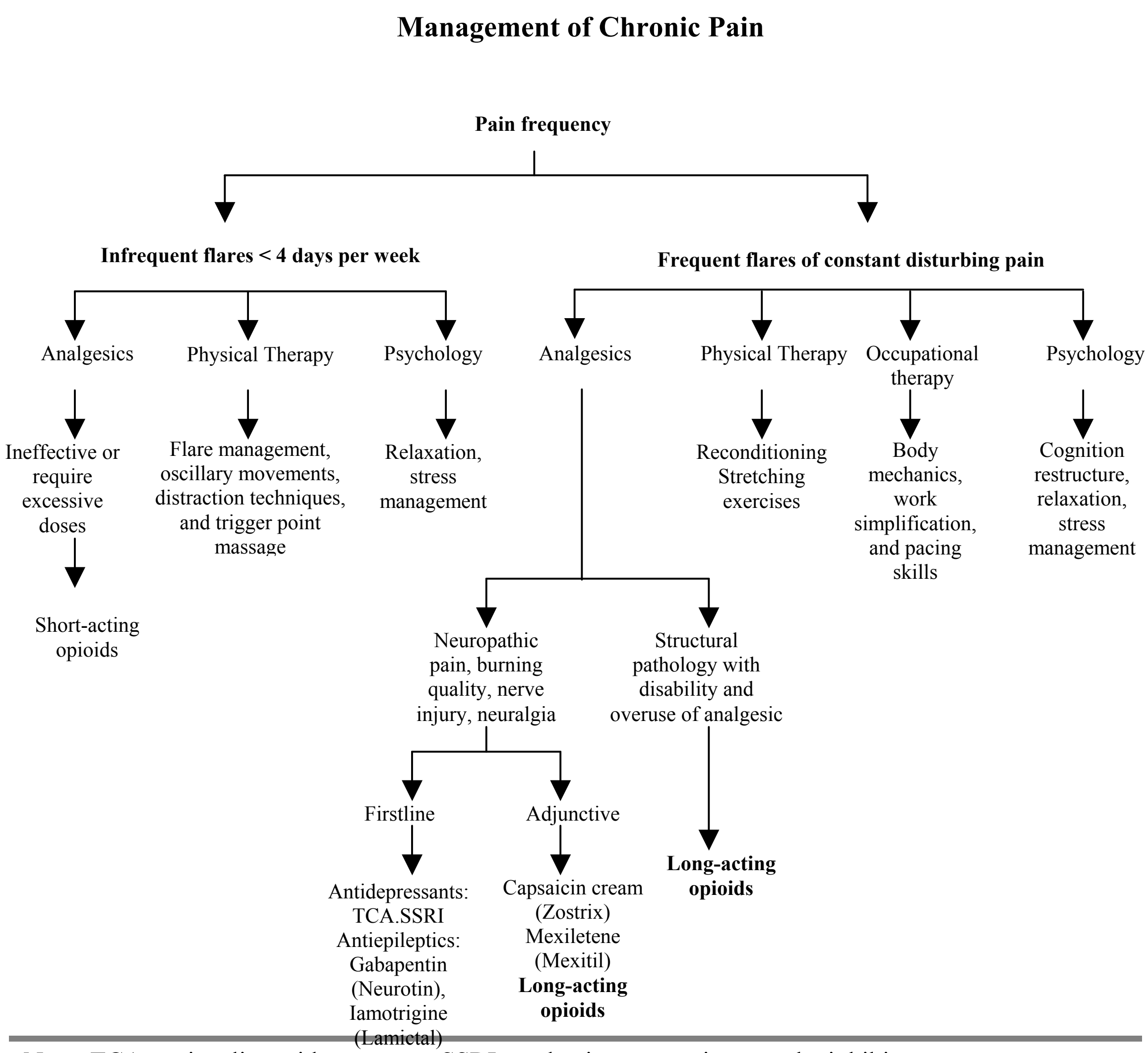
Source:(MacLean et al., 1998)

For individuals suffering from CNMP, the recovery process can be slow and their demand on the health-care system can be large and costly. Aside from treatment costs, these patients often require major disability compensation and absence from work which translates to lost productivity (Andersson, 1999). It is projected that the economic costs associated with treating CNMP will continue to rise as more Americans elect to work beyond 60 years of age and survive into their 80s (Gallagher, 1999; Scanlon& Chugh, 2004). Future studies should focus on collecting pharmacoeconomic data as it relates to the direct, nondirect, and indirect costs of treating CNMP syndromes. The information gathered can enable researchers to better understand the impact of costs of chronic pain from the patient, health system, and societal perspectives.

2.3 Therapeutic Options to Treat CNMP

Many therapeutic alternatives are available to treat CNMP. Most treatment regimes used for chronic pain generally involve a multidisciplinary approach, utilizing both pharmacologic and non-pharmacologic modalities (Figure 2.5).

Figure 2.5 **Algorithm for the Management of Chronic Pain**



Note: TCA = tricyclic antidepressants; SSRI = selective serotonin reuptake inhibitors
Source: Adapted from (Marcus, 2000)

Research demonstrates that multidisciplinary programs incorporating non-pharmacologic therapies with pharmacologic therapies provide a comprehensive approach to managing chronic pain and improving functional outcomes in patients with moderate to severe pain (Allegrante, 1996; American Pain Society, 2000; Dickinson *et al.*, 2000; Baumann, 2002). Physical therapy, occupational therapy, and behavioral approaches are often utilized to manage the underlying pain condition and symptoms associated with CNMP (e.g., depression, sleep disturbances, anxiety, and other sociopyschological conditions) (Allegrante, 1996). The goals of incorporating many of these strategies are pain reduction, improved physical and mental functioning, and improved overall quality of life (Marcus, 2000).

2.3.1 Non-Pharmacologic Therapy

Non-pharmacologic therapies, also known as adjunctive therapy, can play an important role in relieving moderate to severe CNMP, especially when used in conjunction with pharmacologic therapy. Physical, psychoeducational and other multidisciplinary interventions have been shown to help patients cope with various pain syndromes (Allegrante, 1996; Marcus, 2000; Baumann, 2002). The pain goals of non-pharmacologic therapy are consistent with those of pharmacologic modalities. They are to prevent disability, restore physical function, improve social functioning, and improve overall mental well-being of the patient (American Pain Society, 2000; Dickinson *et al.*, 2000; Baumann, 2002).

Traditional adjunctive therapies used to manage chronic muscoskeletal pain include acupuncture, biofeedback, cold (superficial), cold laser, electrotherapy (e.g., transcutaneous electrical nerve stimulation [TENS]), exercise, heat (superficial or deep), splints and braces, and topical agents (e.g., capsaicin) (Allegrante, 1996). Psychoeducational adjunctive interventions may also be used in relieving CNMP. This treatment modality focuses on patients experiencing psychological side effects and depression that can often arise among CNMP patients. Pyschoeducational therapies include cognitive-behavioral interventions, family and social support, patient education, and psychotherapy. Other adjunctive interventions include: assistive devices, hypnosis, relaxation, stress management, and therapeutic massage (Allegrante, 1996).

2.3.2 Pharmacologic Therapy

Medicinal therapies play a critical role in the management of chronic pain. There are three broad categories of analgesic medications used to treat moderate to severe CNMP: (1) non-opioid analgesics, which includes the nonsteroidal anti-inflammatory drugs (NSAIDs), acetaminophen, dipyrone, and others; (2) adjuvant analgesics, which are described as medications with primary indications other than pain but may be analgesic in selected circumstances; and (3) opioid analgesics (Portenoy, 2000).

Non-Opioid Analgesics

Non-opioid analgesics are widely used to treat chronic pain (Baumann, 2002). This class of drugs includes NSAIDs, the most commonly used method to treat CNMP (Dickinson *et al.*, 2000). Drugs within this class of analgesics are generally used as a first-line therapy in the treatment of mild to moderate pain because they are effective and easily accessible, over the counter (Ehrlich, 2003). Common NSAIDs used to treat chronic pain include acetylsalicylic acid (aspirin), ibuprofen, naproxen and until recently, COX-2 inhibitors. Acetaminophen is also included within this class of analgesics because of its pharmacologic properties (Baumann, 2002).

NSAIDs are a nonspecific type of analgesic that can be used to treat a variety of pain syndromes such as chronic headaches, back pain, arthritis and other pain arising from trauma. NSAIDs work by decreasing the level of inflammatory mediators generated at the site of tissue injury by inhibiting the enzyme cyclooxygenase. This action catalyzes the conversion of arachidonic acid to prostaglandins and leukotrienes which results in a desensitization of nerves to painful stimuli (Sunshine& Olson, 1989).

NSAIDs have a dose-dependent effect and produce no physical dependence or tolerance. However, this class of analgesic does have its limitations. NSAIDs have a ceiling effect on their analgesic potential. Further, as the dose increases so does the potential for adverse events and side effects (Portenoy, 2000). NSAID use has been associated with both minor (dyspepsia, heartburn, nausea, vomiting, anorexia, diarrhea, constipation, flatulence, bloating, epigastric pain, and abdominal pain) and major (bleeding, ulceration, and perforation) gastro-intestinal toxicities (Sunshine& Olson, 1989). Serious side effects of acetaminophen include hepatic damage or failure and aspirin or ibuprofen can cause gastrointestinal bleeding, ulceration, renal damage or renal failure. In addition, new information from recent studies shows a potentially increased risk for cardiovascular events (e.g., heart attack and stroke) among users of some COX-2 inhibitors (Solomon, 2005; Nussmeier, 2005; Motsko, 2006).

Though NSAIDs alone can be effective in treating mild to moderate CNMP, they may not provide sufficient analgesia for moderate to severe cases. As previously mentioned, research has shown that increasing the dose or prolonging the use of these types of medications may prove more harmful than beneficial. Moreover, the unintended side effects of these drugs have been associated with thousands of hospitalizations annually (Dickinson *et al.*, 2000; Portenoy, 2000). As a result, clinicians often seek other, more effective, analgesic options when needed to treat patients with moderate to severe CNMP.

Adjuvant Analgesics

Adjuvant analgesics are a very broad and diverse group of medications that can be used to treat CNMP. These types of drugs are FDA approved for indications other than pain, but may be prescribed as an analgesic in select circumstances (Evans *et al.*, 2003a). Adjuvant drugs can be used alone or in combination with a non-opioid or opioid analgesic to treat chronic pain conditions (AGS Panel on Persistent Pain in Older Persons, 2002). Adjuvant analgesics have been shown to have independent or additive pain relief properties to treat persistent pain syndromes as diverse as daily headache, lower back pain, neuropathic pain, and cancer pain (Portenoy, 2000; Gordon, 2003; DUAL Corp, 2005).

Adjuvant analgesics can be grouped into four broad classes, based on their intended use: (1) multipurpose analgesics— e.g., antidepressants, α_2-adrenergic agonists, and corticosteroids; (2) neuropathic pain analgesics— e.g., local anesthetics, anticonvulsants, GABA agonists, neuroleptics, topical analgesics, calcitonin, and sympatholytics; (3) musculoskeletal pain analgesics— e.g., muscle relaxants and some benzodiazepines; and (4) cancer pain analgesics— e.g., osteoclast inhibitors, radiopharmaceuticals, anticholinergics, and octreotides.

Adjuvant analgesics commonly used to treat moderate to severe CNMP include tricyclic antidepressants, anticonvulsants, N-Methyl-D-Aspartate receptor antagonists, lidocaine, and skeletal muscle relaxants (Portenoy, 2000). These types of drugs may be used in all three stages of the analgesic ladder to enhance the efficacy of NSAIDs and opioids by treating the concurrent symptoms that may exacerbate pain (Portenoy, 2000). However, many adjuvant analgesics have side-effects that require careful titration and frequent monitoring (Portenoy, 2000; Ehrlich, 2003).

2.3.3 Opiate Analgesics

Opiate analgesics (opioids) are a third category of pharmacologic therapy that may be used to treat CNMP. Opioids are a class of drugs (e.g., morphine, codeine, heroin, and methadone) that are derived from the opium poppy plant or are produced synthetically. Opioids primary indication is to relieve pain and they are considered the most powerful class of analgesics that may be used to manage moderate to severe CNMP. They are favored based on their effectiveness, ease of titration, and favorable risk-to-benefit ratio (Antoin& Beasley, 2004; Centre for Addiction and Mental Health, 2005; DiPiro *et al.*, 2005; San Francisco AIDS Foundation, 2005). Other medical uses of opiates include cough suppression, anti-diarrheal and treatment of addiction to other opioids. The use of opiates to manage pain is commonly pursued after NSAIDs and adjunctive therapies have been explored (Baumann, 2002).

Morphine and codeine are the principal components of naturally occurring opioids. Derived from the poppy plant, these two ingredients are extracted from the seed pod of the opium poppy for their analgesic and euphoric properties (Centre for Addiction and Mental Health, 2005). Today, many opiate analgesics used to control pain either contain pure morphine or codeine extracts or are synthetically manufactured (derived from the morphine structure) to induce opium-like effects. Opioids work by binding to specific opioid receptors in the CNS and other tissues found throughout the mid-brain and spinal cord. The analgesic effects produced by opioids are a result of their interaction with at least four different types of CNS receptors: mu (μ), delta (δ), kappa (κ), and sigma (σ). By attaching to these opioid receptors, opiate analgesics can effectively block the transmission of pain messages to the brain (Baumann, 2002; Kumar& Demeria, 2003; Lauretti *et al.*, 2003). The pharmacologic activity of an opioid depends on its affinity for these receptors, to which receptor it binds, and whether the opioid is an agonist or an antagonist (Kumar& Demeria, 2003). The major role in analgesia appears to occur with opioids binding with the μ and κ receptors. A comprehensive review of the pharmacokinetics of opioid analgesics is provided by Di Piro *et al.* (2002).

Opiate analgesics are traditionally divided into three categories: (1) pure-agonists, (2) partial agonists-antagonists, and (3) mixed agonist-antagonists (Baumann, 2002). Prescription opioids belonging to these categories are available in various dosage forms including tablets, capsules, syrups, solutions and suppositories (Table 2.4). The route of administration typically depends on the patient's needs such as level of pain, speed of onset and duration of action (Baumann, 2002; Centre for Addiction and Mental Health, 2005). Most opioids are well absorbed through oral or rectal administration. However, complete absorption may not occur by the GI system and first-pass metabolism in the liver may require the need for higher doses to be administered. Other administration routes include intravenous, subcutaneous, and intramuscular and intrathecal (Baumann, 2002; DUAL Corp, 2005).

Pure-agonists include natural and synthetic opioids like morphine sulfate (MS Contin®), hydromorphone (Dilaudid®), oxymorphone (Numorphan®), levorphanol (Levo-Dromoran®), codeine (Tylenol w/Codeine 3®), hydrocodone (Vicodin®), oxycodone (OxyContin®), methadone (Dolophine HCl®), and fentanyl (Duragesic®). This group of opioids do not have a ceiling effect for their analgesic efficacy nor do they antagonize (reverse) the effects of other pure opioids (Baumann, 2002). Morphine is the most widely used type of opioid analgesic for the treatment of moderate to severe pain due to its availability, the range of doses offered, and its low cost.

Table 2.4 Opiate Analgesics Classifications

Class and Generic Name	Route	Description
Pure Agonists		
Morphine like Agonists		
Morphine	PO,IM,IV,SQ, R	Drug of choice for severe pain
Hydromorphone	PO,IM,IV,SQ, R	Used for severe pain; More powerful than morphine (No advantages over morphine)
Oxymorphone	PO,IM,IV,SQ, R	Used for severe pain (No advantages over morphine)
Levorphanol	PO,IM	Used for severe pain
Codeine	PO,IM,IV,SQ, R	Used for moderate pain
Hydrocodone	PO	Used for moderate/ severe pain
Oxycodone	PO,IM,IV	Used for moderate/ severe pain
Meperidine-Like Agonists		
Meperidine	PO,IM,IV	Used for severe pain
Fentanyl	IM,TD,TM	Used for severe pain; do not use in acute pain; transmucosal for "breakthrough" cancer pain
Methadone-Like Agonists		
Methadone	PO,IM	Effective for severe chronic pain
Propoxyphene	PO	Used for moderate pain; weak analgesics
Agonist-Antagonist Derivatives		
Pentazocine	PO,IM	3rd line agent for moderate to severe pain;
Butorphanol	IM,IV,IN	2nd line agent for moderate to severe pain;
Nalbuphine	IM,IV	2nd line agent for moderate to severe pain;
Buprenorphine	IM,IV	2nd line agent for moderate to severe pain;
Dezocine	IM,IV	2nd line agent for moderate to severe pain;
Antagonists		
Naloxone	IV	Used when reversing opiate side effects in patients needing analgesia
Central Analgesic		
Tramadol	PO	Used in treating neuropathic pain

Legend: IM = Intramuscular; IN = Intranasal; IV = Intravenous; PO = By mouth; R = Rectal; SQ = Subcutaneous; TD = Transdermal; TM = Transmucosal

Source: (Baumann, 2002)

Partial agonists-antagonists are agents that stimulate the analgesic portion of opioid receptors while blocking or having little or no effect on toxicity (Baumann, 2002). This group of opiates include buprenorphine and may be used as second line therapy among pain patients (Baumann, 2002). Partial agonists-antagonists have lower abuse potential than pure-agonists, however the side-effects of this class of analgesics include hallucinations and dysphoria. Included in the partial agonists-antagonists drug class, *opioid antagonists* are agents most often used to reverse the effects of agonists and agonist-antagonist derived opioids. This class of analgesics (e.g., naloxone) does this by binding competitively to opioid receptors to prevent an analgesic response (Baumann, 2002).

Mixed agonists-antagonists are another type of opiate analgesics that may be used to treat pain. They include such drugs as butorphanol (Stadol®), dezocine (Dalgan®), nalbuphine (Nubain®) and pentazocine (Talwin®) (Baumann, 2002). Mixed agonists-antagonists have limited use among chronic pain patients because of their ceiling effect for analgesia which results in the analgesic effect not increasing with dose escalation.

An emerging fourth class of opiate analgesic that may be used to treat CNMP are *central analgesics*. This small class of synthetic opioids (e.g., Tramadol) exhibits μ receptor activity and a mechanism of action that inhibits the reuptake of serotonin and norepinephrine. Central analgesics drugs such as Tramadol (Ultram®) are reported to be effective in managing neuropathic pain (Kumar& Demeria, 2003). Side effects are similar to traditional opioids.

Dosage and scheduling. Opioid effectiveness varies among patients and is dependent on pain condition type and patient physiology (McPherson *et al.*, 2004). Dosage for one type of opioid that provides effective analgesia for a particular patient may not be efficacious in another patient experiencing similar symptoms. Repeated dose adjustments may be necessary if the initial dosage does not provide adequate pain relief. If this occurs, experts recommend titrating opioid dosages upwards until adequate pain relief is achieved or intolerable adverse events occur. Refer to Table 2.5 for an illustration of equianalgesic dosages of selected opioids.

Table 2.5 Equianalgesic Dosages of Opioids

	Dose Equianalgesic to 10 mg of IM Morphine (mg)	
Opioid	**IM**	**Oral**
Codeine	130	200
Oxycodone	15	30
Propoxyphene	100	50
Morphine	10	30
Hydromorphone	2 – 3	7.5
Methadone	10	3 – 5
Meperidine	75	300
Oxymorphone	1	NA
Levorphanol	2	4
Fentanyl Transdermal	100 µ/hr = 2 - 4 mg/hr of IV morphine	NA

IM = intramuscular; IV = intravenous; NA = not available
Source: (McPherson et al., 2004)

Risks and side effects. All three classes of opioids exhibit related pharmacologic attributes and affect the CNS and gastrointestinal system. Common side effects include mood changes, sedation, respiratory depression, nausea, vomiting, constipation, dependence, and tolerance (Table 2.6).

Table 2.6 Side Effects of Opioid Analgesics

Effect	Manifestation
Mood changes	Dysphoria, euphoria
Somnolence	Lethargy, drowsiness, apathy, inability to concentrate
Stimulation of chemoreceptor trigger zone	Nausea, vomiting
Respiratory depression	Decreased respiratory rate
Decreased gastrointestinal motility	Constipation
Increase in sphincter tone	Bilary spasm, urniary retention (varies among agents)
Histamine release	Urticaria, pruritus, rarely exacerbation of asthma (varies among agents)
Tolerance	Larger doses for same effect
Dependence	Withdrawal symptoms upon abrupt discontinuance

Source: (adapted from Baumann, 2002)

The severity of these side effects vary among opioid classes and agents (Baumann, 2002). Other serious problems related to opioid therapy include weight gain, myoclonus, adrenal suppression, immunosuppression, and hypogonadism (Antoin& Beasley, 2004).

Prolonged exposure to opioid analgesics may result in physical dependence, tolerance, and possibly addiction (Arkinstall *et al.*, 1995; Baumann, 2002; Kumar& Demeria, 2003). Sudden cessation of opioids can produce drug withdrawal symptoms among patients. As a result, patients who become physically dependent should be tapered off opiate analgesics over a period of time to eliminate or reduce drug withdrawal side effects. Tolerance may also develop from prolonged exposure to opiates. The cause of opiate tolerance is unknown, however patients who are exposed to opioids experience a gradual decrease in analgesic effect over time. Consequentially, increased dosage of the drug or switching to another type of opiate analgesic may be required to maintain adequate pain control (Kumar& Demeria, 2003). Under medical supervision, there is little risk of addiction to opiates. Study findings indicate, that in patients without a history of substance abuse, long term use of opiate analgesics rarely leads to addiction (Zenz *et al.*, 1992; Kumar& Demeria, 2003). Risks for addiction to opioids will be discussed in more detail in Section 2.7.1.

2.4 Role of Controlled-Release Opioids (CR opioids)

Management of moderate to severe chronic pain often includes the use of opioids in combination therapies, but their effectiveness is dependent upon clinician management techniques and patient adherence (Simpson *et al.*, 1997). *Short-acting opioids* also known as “normal-release” or “immediate-release” opioids are seen as an effective method in controlling both acute and chronic pain (Baumann, 2002). Short-acting opioids such as Vicodin® (hydrocodone and acetaminophen) are usually taken every two to four hours and are often useful in managing patients with intermittent and breakthrough pain, that is pain that “breaks through” the level of relief provided by ongoing analgesia (Table 2.7).

Table 2.7 Opioid Analgesics

	Generic Name	Brand Name
Short-Acting	Morphine	MSIR®, Roxanol®
	Oxycodone	OxyIR®, Oxyfast®, Endocodone®
	Oxycodone (with acetaminophen)	Roxilox®, Roxicet®, Percocet®, Tylox®, Endocet®
	hydrocodone (with acetaminophen)	Vicodin®, Lorcet®, Lortab®, Zydone®, Hydrocet®, Norco®
	Hydromorphone	Dilaudid®, Hydrostat®
Long-Acting	Morphine	MSContin®, Oramorph SR®, Kadian®, Avinza®
	Oxycodone	Oxycontin®
	Fentanyl	Duragesic Patch®
	Hydromorphone	Palladone®

Source:(Granville et al., 2005)

Controlled-release opioids (CR opioids), also known as "sustained-release" or "long-acting" opioids, are a highly potent form of opiate analgesic. This group of opiate analgesics was designed to provide analgesia in the same manner as immediate-release (short-acting) opioids but over longer periods of time, hence requiring less administration (Roth *et al.*, 2000). Available evidence suggests that long-acting opiate analgesics, when used under the right circumstances, can hold considerable potential in helping moderate to severe CNMP patients better manage their pain (Moulin& Iezzi, 1996). As a result, longer acting opiates may be preferred over short-acting agents in patients who require around-the-clock analgesic therapy because they allow less frequent dosing, potentially reducing pain fluctuations (e.g., break-through pain), and improving compliance (Arkinstall *et al.*, 1995; Davis *et al.*, 2003; Goli& Finley, 2005).

The decision to use CR opioids for moderate to severe CNMP is influenced by many factors: (1) the condition causing pain, (2) the severity and intractability of pain, (3) the relationship between the physician and patient, (4) the availability of other treatments,

(5) the physician's type of practice, (6) the regulatory climate of the community, (7) the acceptance of opioid analgesic within the community, (8) the availability and access to pain specialists, (9) the patient's desire for opioid therapy, (10) the physician's experience, (11) the patient addiction history, and (12) the patient's social environment (Belgrade, 1999).

Experts agree that CR opioids may be particularly beneficial among CNMP patients that require sustained analgesia (Portenoy, 1996a). Available data suggest that this class of opiates holds considerable potential in effectively managing CNMP (Simpson *et al.*, 1997; Allan *et al.*, 2001; Glajchen, 2001; Washington State Department of Labor and Industries, 2002; Davis *et al.*, 2003; Lauretti *et al.*, 2003; Fisher, 2004a). Though previous research is unclear as to how much more effective CR opioids are in comparison to their short-acting counterparts, several studies suggest that patients are able to obtain a better response to pain control when given around-the-clock analgesic therapy (Arkinstall *et al.*, 1995; Simpson *et al.*, 1997; Allan *et al.*, 2001; Glajchen, 2001; Davis *et al.*, 2003; Lauretti *et al.*, 2003; Fisher, 2004a). Other research has shown that significant improvements in quality of life and reduction in opioid side-effects may be achieved among CNMP patients taking CR opioids compared to shorter acting opioids (Simpson *et al.*, 1997; Caldwell *et al.*, 1999; Hale *et al.*, 1999; Peat *et al.*, 1999; Salzman *et al.*, 1999; Caldwell *et al.*, 2002; Veterans Health Administration, 2003).

A primary clinical benefit of CR opioids is that by virtue of their prolonged pain relief, they eliminate the need to take a pill every two to four hours. Scheduled dosing of these types of medications requires administration once or twice a day (McPherson *et al.*, 2004). Refer to Table 2.8 for dosage frequency and available dosages for selected opioids. In addition, previous studies show that fewer side effects such as reduced euphoria, potential for addiction, and sleep disturbances are seen when using these types of opioids (Otis& Fudin, 2005).

CR opioids are available in a number of different formulations. Morphine (MS Contin® and Avinza®), hydromorphone, (Palladone™), oxycodone (OxyContin®), and transdermal fentanyl (Duragesic®) are the most commonly used CR opioids used to treat pain (Goli& Finley, 2005). Common routes for administration of these types of opioids are by mouth, rectal, transdermal, or infusion pump.

Table 2.8 Selected CR Opioid Analgesics

Opioid	Dosing Frequency (hr)	Available Dosages (mg)
Fentanyl (Duragesic®)	72	2.5 (25 μ/hr) 5 (50 μ/hr) 7.5 (75 μ/hr) 10 (100 μ/hr)
Hydromorphone (Palladone™)	24	12, 16, 24, 32
Morphine		
(MSContin®)	8-12	15, 30, 60, 100, 200
(Kadian®)	12	20, 30, 60, 50, 100
(Avinza®)	24	30, 60, 90, 120
Oxycodone (Oxycontin®)	12	10, 20, 40, 80, 160

Source: Adapted from (McPherson et al., 2004)

"Extended-release morphine is the standard against which other CR opioids are measured" (Otis& Fudin, 2005). The bioavailability of this type of opiate analgesic is less than 40 percent. However, due to presystemic metabolism, the bioavailability of morphine can vary greatly among individuals. CR formulations of morphine are available in a wide range of dosages to provide sustained levels of analgesia during a 12 to 24 hour period (Allan *et al.*, 2001).

Hydromorphone is a semi-synthetic opioid which is more potent than morphine and is generally used among patients that experience intolerable side effects to morphine (Goli& Finley, 2005). Dosage frequency for the drug is once daily. Until recently, the long-acting brand name version, Palladone™ was available by prescription within the United States. However, in June of 2005, the Food and Drug Administration (FDA) requested that sale of the drug be voluntarily suspended by the manufacturer. Co-ingestion of Palladone with alcohol resulted in dangerous peak plasma concentrations of the drug. As a result, the FDA concluded that that the overall risk to benefit ratio was unfavorable (FDA, 2005).

CR oxycodone was designed as an alternative to morphine. Also more potent than morphine and originally designed as a second-line treatment to morphine, CR oxycodone is gaining wider acceptance among clinicians as a first-line schedule II option (Davis *et al.*, 2003). This type of CR opioid is seen as a good option for patients who may have a previous history of being intolerant to morphine (Otis& Fudin, 2005). CR oxycodone is commonly administered orally or rectally in tablet or pellet form and provides a controlled delivery of the drug over a 12-hour period (Davis *et al.*, 2003; Purdue Pharma LP, 2003).

Another commonly used CR opioid is the transdermal fentanyl patch. Fentanyl is a highly lipophilic opioid which is readily absorbed into the bloodstream. The transdermal delivery system provides continuous systemic delivery of opiate over a 72-hour period (Simpson *et al.*, 1997; Allan *et al.*, 2001; Janssen Pharmaceutica Products L.P., 2003; Otis& Fudin, 2005). Opioids with longer half-lives, such as methadone and levorphanol, are also used to treat chronic pain. These opiate analgesics are prescribed to provide around-the-clock relief for an extended period of time to prevent pain relapse that can result from gaps in medication adherence (Arkinstall *et al.*, 1995; PDR Health, 2005).

Limitations of CR opioids

The side effects and risks associated with CR opioids are similar to those of short-acting opiate analgesics. Common side effects include mood changes, sedation, respiratory depression, nausea, vomiting, constipation, dependence, and physical tolerance. However, one serious risk associated with this type of opiate analgesic is due to the metabolic half-life. Research suggests that CR opioid formulations with long half-lives may pose a problem with delayed toxicity when the interval between doses is shorter than the drug's half-life (Goli& Finley, 2005). This concern emphasizes the importance of safe administration of CR opioids. For example, oral formulations of CR opioids require tablets not to be physically altered or damaged prior to swallowing. Tablets that are crushed, broken or chewed prior to swallowing will result in large doses of opiate intended for slow absorption to be released at once. This higher dosage could result in overdose and possible death. Similarly, capsule preparations that contain pellets, which may either be swallowed whole or opened so that the pellets can be sprinkled on soft foods, should not be crushed or chewed. Crushing, chewing, or dissolution of the pellets may also result in overdose or death (Roth, 2002; Goli& Finley, 2005). The use of long-acting opioids can be an essential step to effective CNMP management but many physicians still have concerns regarding drug efficacy, patient addiction, tolerance, physical dependency and side-effects (Simpson *et al.*, 1997; Dickinson *et al.*, 2000).

2.5 Pain Management Guidelines

Recent pain management guidelines and evidenced-based studies have recommended the use of "long-acting" opioids in certain chronic pain conditions (American Academy of Pain Medicine and the American Pain Society AAPM&APS, 1997; National Pharmaceutical Council, 2001; FSMB, 2003; Gardner-Nix, 2003; Veterans Health Administration, 2003; Wisconsin Medical Society: Task Force on Pain Management, 2004). However, health practitioners have been cautious in adopting the treatment guidelines that encourage the use of opiate analgesics among patients with moderate to severe CNMP. Physicians have expressed a need for a "gold-standard" or general guidance in opioid prescribing protocols when used in the treatment for CNMP (AAPM & APS, 1997).

While no particular treatment program for CNMP has been universally endorsed by any of the medical guideline-issuing organizations, numerous guidelines have been created to assist physicians in treating chronic pain patients (JCAHO, 2000; National Pharmaceutical Council, 2001). The Agency for Healthcare Research and Policy (AHRQ) formerly known as the Agency for Health Care Policy and Research (AHCPR), introduced the first U.S. clinical practice guidelines for pain management in 1992 (Table 2.9). Since that time, other groups such as the American Society of Anesthesiologists (ASA), the American Pain Society (APS), and the American Academy of Family Physicians (AAFP) have produced an assortment of guidelines, adopted by physicians and other health care providers in managing CNMP patients (National Pharmaceutical Council, 2001). Each of the chronic pain guidelines listed in Table 2.9 contain a mixture of consensual strategies and differences in treatment approaches for patients suffering from CNMP, yet, they are all guided by two important objectives: (1) patient comfort, and (2) improved psychological and social functioning (Portenoy, 1996a; Sanders *et al.*, 1999; American Pain Society, 2000; Wisconsin Medical Society, 2004).

Table 2.9 Examples of Practice Guidelines for Management of Chronic Pain

1992	AHCPR	Acute Pain Management: Operative or Medical Procedures and Trauma Clinical Practice Guideline No. 1 (Publication No. 92-0032)
1995	ACR	Guidelines for the Medical Management of Osteoarthritis
1996	ASA	Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists
1996	ASA	Practice Guidelines for Chronic Pain Management
1997	ASA	The Management of Chronic Pain in Older Persons
1997	UIGNIC	Acute Pain Management
1998	AGS	The Management of Chronic Pain in Older Persons
1999	ICSI	Adult Low Back Pain
1999	AAOS	Clinical Guideline on Hip, Knee, and Wrist Pain
1999	APS	Guideline for the Management of Acute and Chronic Pain in Sickle Cell Disease
1999	APS	Principles of Analgesic Use in The Treatment of Acute Pain and Cancer Pain Diagnosis and Management
1999	AMDA	Chronic Pain Management in the Long Term Care Setting
2000	AAFP	Treatment of Non-Malignant Chronic Pain
2000	ICSI	Assessment and Management of Acute Pain Disease of the Knee

Abbreviations: AAFP: American Academy of Family Physicians; AAOS: American Academy of Orthopaedic Surgeons; ACR: American College of Rheumatology; AGS: American Geriatrics Society; AHCPR: Agency for Health Care Policy and Research; AMDA: American Medical Directors Association; APS: American Pain Society; ASA: American Society of Anesthesiologists; ICSI: Institute for Clinical Systems Improvement; UIGNIC: University of Iowa Gerontological Nursing Interventions Center.
Source: (National Pharmaceutical Council, 2001)

In a 1997 joint consensus statement, the American Academy of Pain Medicine (AAPM) and the APS recognized opioids as playing an essential role in managing both the social and economic costs of CNMP (American Academy of Pain Medicine and the American Pain Society AAPM&APS, 1997). The group acknowledged that chronic pain is often managed inadequately due to suboptimal treatment methods and that a standard principle of practice should be developed for clinicians to follow when deciding to use opiate analgesics (Dickinson *et al.*, 2000).

Most pain management guidelines acknowledge the need for good clinical practice when prescribing opiate analgesics to treat chronic pain. Many of these guidelines emphasize that treatments must be individually tailored to chronic pain patients with consideration given to different treatment modalities. The pain practice guidelines outline the best methods to administer opioid therapy (e.g., long-term use) and underline the importance of monitoring patients to evaluate treatment effectiveness and patient functioning. Many of the guidelines agree that the use of opioids should be considered only after other treatment alternatives have been explored. However, minimal guidance is provided on which patients should receive opioids or the type of criteria that should be used to select them (Dickinson *et al.*, 2000). Table 2.10 summarizes the 2001 JCAHO recommendations for prescribing opioids to CNMP patients (National Pharmaceutical Council, 2001).

Table 2.10 JCAHO Recommendations for Opioid Therapy in Patients with CNMP

Before treatment:

1. Perform comprehensive assessment, including a pain history and assessment of the impact of the pain, a directed physical examination, a review of prior diagnostic study results or interventions, a drug history (i.e., past abuse), and an assessment of coexisting diseases or conditions.
2. Consider obtaining a second opinion from a physician or psychologist with expertise in pain management and use of interdisciplinary team.
3. Optimize nonpharmacologic and nonopioid therapies.
4. Inform patient of potential risks of use of controlled substances, including addiction (informed consent).
5. Agree on issues including how drugs will be provided, acceptable number of rescue doses, pharmacy to be used for prescription refills, and the follow-up interval.

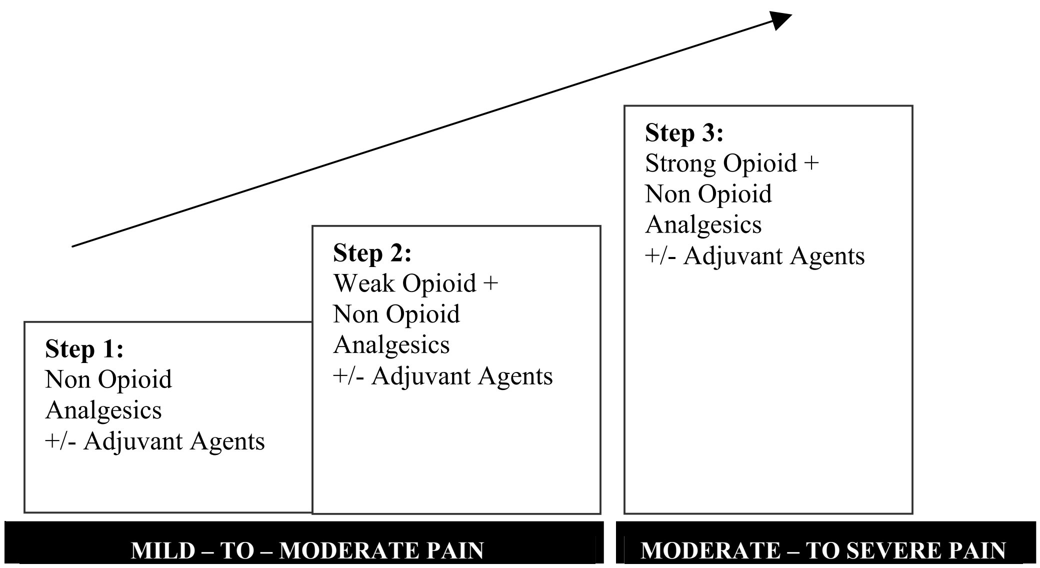
During treatment:

1. Administer opioids primarily via oral or transdermal routes, using long-acting medications when possible.
2. Use a fixed dosed ("around-the-clock") regimen.
3. Perform careful drug titration, balancing analgesia against side effects.
4. Continue efforts to improve analgesia via complementary approaches (e.g., behavioral approaches, formal rehabilitation program, and other medications).
5. Consider use of hospitalization for pain that is not treated by transient, small dose increments.
6. Monitor for evidence of drug hoarding, unauthorized dose increases, and other aberrant behavior. Reconsider therapy in the occurrence of such behaviors.
7. Perform frequent follow-up evaluation to monitor analgesia, side effects, functional status, quality of life, and any evidence of medication misuse.
8. Consider use of self-report instruments (e.g., pain diary).
9. Carefully document the overall pain management treatment plan and include the reason for opioid prescribing, any consultations received, and results of periodic review of patient's status.

Source: (National Pharmaceutical Council, 2001)

Many of the recent chronic pain guidelines have been modeled after the 1986 World Health Organization's (WHO) analgesic ladder (World Health Organization, 1990). Originally developed for treating terminally-ill or end-of-life patients, the WHO analgesic ladder outlines the pharmacologic treatment strategies clinicians may follow when treating chronic pain patients. Today's advocates of the analgesic ladder point out that the choice of analgesic should be based on the severity of the pain rather than the stage of the patient's disease (Gardner-Nix, 2003; McCarberg, 2004). Further, proponents recognize the need for analgesics to be taken regularly and the dose gradually increased, as necessary. In the absence of clear CNMP guidelines, the WHO tool has been utilized by physicians and medical organizations as a guide for CNMP management (Figure 2.6).

Figure 2.6 **World Health Organization Analgesic Ladder**



Source: Adapted from (McCarberg, 2004)

As depicted in the ladder, non-opioids analgesic drugs are generally the first-line treatment for pain. The use of acetaminophen or NSAIDs are widely used first-line therapy among patients suffering from mild to moderate pain (Step 1). The use of mild opioid analgesic agents (e.g., codeine) are recommended in Step 2, while the more potent opiate analgesics (e.g., CR morphine, CR oxycodone) are reserved for Step 3. Adjuvant therapy such as antidepressants, anticonvulsants and muscle relaxants may be used during each step to assist with pain symptoms (Gardner-Nix, 2003).

Figure 2.7 illustrates Gallagher's flow diagram for implementing and assessing opioid therapy in chronic pain management.

Figure 2.7 **Implementing and Assessing Opioid Therapy in Chronic Pain Management**

Thorough history and physical examination

↓

Appropriate screening to establish patient as a candidate for opioid therapy → Consider consultation or referral

↓

Risk of Abuse

Complete informed consent → Complete opioid treatment agreement with patient

↓

Each Patient Encounter

Select opioid formulation and dosage → Complete/update medical record

- Medical history and physical examination
- Diagnostic, therapeutic, and laboratory results
- Evaluations and consultations
- Treatment goals
- Discussion of risks and benefits
- Informed consent
- Treatments
- Medications, including date, type, dosage, and quantity prescribed
- Instructions and agreements
- Periodic reviews

↓

Assure medication compliance

- Provide medications only when prescription is due
- One physician will provide all pain medication prescriptions
- One pharmacy will be used to obtain all pain medications
- Provide limited supply (e.g., 1 or 2 weeks)
- Use the minimum effective dose
- Conduct planned/random dosage count
- Conduct unscheduled office visits
- Perform random urine toxicology screening
- Conduct behavior assessment
- Wean periodically to reassess pain control
- Use nonpsychotropic pain medications when possible

↓

Monitor efficacy and safety

- Function improved by 50%
- Pain reduced to moderate level (6/10)
- Reduction in excessive analgesic overuse
- Reduction in emergency department visits
- Side effects acceptable with/without management

Source: (Gallagher, 2004)

An example of the New Hampshire Medical Society (NHMS) guidelines for using controlled substances in CNMP patients are outlined in Table 2.11. These guidelines were taken from the Federation of State Medical Boards' (FSMB) "Model Policy for the Use of Controlled Substances for the Treatment of Pain" and incorporated into the medical organization's chronic pain treatment practices (the role of the FSMB will be discussed in Section 2.7.2). The guidelines are not intended to define complete or best practice, but rather to communicate what the medical society considers to be within the boundaries of professional practice.

As of January 2004, 22 of the U.S. state medical boards have adopted policies, rules, regulations, or statutes reflecting the FSMB model guidelines into their state pain management policies (FSMB, 2003). No information was found that acknowledged the Texas Medical Board's (TMB) endorsement of the guidelines.

In an April 2005 TMB official newsletter statement, sent out to Texas physicians and state medical associations, the TMB formally acknowledged the value of opioids in pain management. In the newsletter, the TMB stated that they "recognized that opioids (narcotics) and other scheduled-controlled substances, are indispensable for the treatment of pain; and are useful for relieving and controlling many other distressing symptoms that patients may suffer" (Texas Medical Board, 2005). The TMB further clarified that "it is the position of the Board that these drugs be prescribed for the treatment of these symptoms in appropriate and adequate doses after an appropriate diagnosis is made" (Texas Medical Board, 2005).

Table 2.11 New Hampshire Medical Society (NHMS) Guidelines for Evaluating the Physician's Treatment of Pain, Including the Use of Controlled Substances

1. Evaluation of the Patient

A medical history and physical examination must be obtained, evaluated, and documented in the medical record. Pain intensity, current and past treatments for pain, co-morbidities, physical and psychological functioning, and history of substance abuse should be considered.

2. Treatment Plan

A written treatment plan stating objectives to be used to determine treatment success (i.e., pain relief and improved physical and psychosocial function) should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities should be considered.

3. Informed Consent and Agreement for Treatment

A discussion of the risks and benefits of the use of controlled substances with the patient, family members or persons designated by the patient guardian. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including: urine/serum medication levels screening when requested; number and frequency of all prescription refills; and reasons for which drug therapy may be discontinued (e.g., violation of agreement).

4. Periodic Review

A periodic review of the course of pain treatment and any new information regarding etiology of the pain or patient's health. Continuation or modification of controlled substances for pain management depends on the physician's evaluation of progress toward treatment objectives. Adherence to treatment and satisfactory response to treatment should be considered in future treatment.

5. Consultation

Referral to a pain specialist for additional evaluation and treatment should be considered in order to achieve treatment objectives. Special attention should be given to patients at risk for medication misuse or diversion, patients with a history of substance abuse or with a co-morbid psychiatric disorder.

6. Medical Records

Accurate and complete records to include the medical history and physical examination; diagnostic, therapeutic and laboratory results; evaluations and consultations; treatment objectives; discussion of risks and benefits; informed consent; treatments; medications (including date, type, dosage and quantity prescribed); instructions and agreements; and periodic reviews. Records should remain current and be maintained in an accessible manner and readily available for review.

7. Compliance With Controlled Substances Laws and Regulations

Must be licensed in the state and comply with applicable federal and state regulations to dispense controlled substances. Refer to the Physicians Manual of the U.S. Drug Enforcement Administration for specific rules governing controlled substances as well as applicable state regulations.

Source:(New Hampshire Medical Society, 1998)

Traditionally, health practitioners have been cautious in adopting the treatment guidelines that encourage the use of opiate analgesics among patients with moderate to severe CNMP. This prudence is due, in part, to physicians' knowledge and beliefs regarding the use of opioids and lack of a "gold standard" for the clinical practice in chronic pain management. Many pain specialty organizations acknowledge a need for some type of clinically accepted guidelines for CNMP management (American Pain Society, 1995; American Academy of Pain Medicine and the American Pain Society AAPM&APS, 1997; FSMB, 2003; AMA, 2004). While different health organizations have developed guidelines for opioid therapy in CNMP, the AAPM and the APS emphasize that health providers recognize these guidelines as an additional strategy to basic principles of good professional practice.

The therapeutic options used in CNMP management have traditionally been focused on a wide array of therapeutic interventions designed to decrease pain and simultaneously improve function (Burchman& Pagel, 1995). Many of the guidelines have been developed and promoted by pain practice associations, government health agencies, medical organizations and practicing physicians (Canadian Pain Society, 1998; American Pain Society, 2000; Ehrlich, 2003; AMA, 2004; Wisconsin Medical Society: Task Force on Pain Management, 2004).

2.6 Role of Family Physicians

Family physicians (FPs) are in a unique position to provide an essential level of palliative care to patients unable to achieve adequate pain control. Guidelines issued by JCAHO have increased the FP's role in managing CNMP. However, as previously discussed, no specific treatment program for CNMP has been endorsed by any of the medical guideline-issuing organizations (JCAHO, 2000; National Pharmaceutical Council, 2001). As a result, FPs are often required to select pain guidelines for which they are comfortable using. They are expected to be capable of managing routine chronic pain and be able to identify situations for which opioid analgesics are appropriate (Marcus, 2002).

As the coordinator of care for many CNMP patients, FPs must be able to identify those chronic pain conditions (e.g., neuropathic pain, joint pain, lower back pain) that require specific therapy. FPs should be able to identify co-morbid psychiatric illnesses, evaluate musculoskeletal abnormalities, evaluate physical disability, and inform patients of outcome expectations from therapy (Marcus, 2002). CNMP management plans implemented by FPs should include treating co-morbid illnesses and disability, with consideration of subspecialty referrals for appropriate care and therapy (e.g., psychologic or psychiatric care, physical or occupational therapy).

Pharmacotherapy recommendations that sanction the use of opioids should be contingent on available pain management guidelines and the patient's compliance with the treatment program (Marcus, 2002). According to pain management experts, FPs should be able to understand that the use of CR opioids be considered only in patients who have a clear medical diagnosis, disabling pain, no recent or active history of medication or alcohol abuse, demonstrated compliance with treatment recommendations, and pain that has not responded to initial analgesic or neuropathic medication therapies (Portenoy, 1996b; Marcus, 2002, 2003). A recent AAFP article discussing CNMP management in the primary care setting recommends that FPs use CR opioids for patients suffering from constant disabling pain (Marcus, 2002).

When necessary, FPs may turn to pain specialists or interdisciplinary pain management teams to assist them with managing their CNMP patients. These teams usually consist of a physician specializing in pain management (e.g., neurologist, anesthesiologist, family physician, internist, physical medicine and rehabilitation specialist), a clinical health psychologist, and a physical therapist. Often, patients whose chronic pain is unresolved by family physicians are sent to pain specialists. Referral to pain specialists should be considered when the FP becomes uncomfortable with the current treatment protocol or outcome (Jamison *et al.*, 2002).

The complexity of CNMP management is a challenge faced by many FPs. Successful CNMP management depends on the ability of FPs to understand and utilize the fundamental pain management concepts governing the pathophysiology, psychodynamics, and diagnostic and therapeutic modalities associated with chronic pain syndromes (Bergman& Werblun, 1978). As previously discussed, the use of analgesics, particularly CR opioids, requires frequent patient assessment and a readiness to re-evaluate the patient's therapeutic plan when either inadequate relief or adverse effects arise.

2.7 Barriers Toward Prescribing CR opioids for CNMP

Many health care experts agree that using opiate analgesics should be considered the next logical step in the management of CNMP when other nonpharmacologic and non-opiate analgesic alternatives have been exhausted. Despite recently published pain management guidelines and evidenced-based studies that recommend the use of "long-acting" opioid analgesics, many physicians are reluctant to prescribe these types of opioids, even when appropriate indications exist (Gardner-Nix, 2003).

Obstacles to prescribing CR opioids include inadequate education and training, reinforced by concerns of patient addiction, potential for abuse or misuse, side-effects, and fear of regulatory scrutiny (Weinstein *et al.*, 2000b; Morley-Forster *et al.*, 2003; Gallagher, 2004). Based on the literature, these barriers extend to both pain specialty and non-pain specialty physicians (i.e. primary care physicians). However, findings from several published studies have shown that these barriers can have a greater impact among primary care physicians decision-making to use opioids for chronic pain (Morley-Forster *et al*, 2003; Turk, 1996; Turk *et al*, 1994). Issues causing physician uncertainty, some valid and some based solely on knowledge deficits or misconceptions, may act as barriers to appropriate prescribing of CR opioids (Table 2.12). Experts believe that knowledge gaps, fear of patient addiction, deficient pain-assessment skills, fear of regulatory scrutiny and timidity in prescribing may lead to "opioid-phobia," a prejudice against the use of opioid analgesics (Glajchen, 2001).

Table 2.12	Common Physician Concerns Regarding the Use of Opioids for Chronic Pain
1.	Fear of causing addiction; misunderstanding of the definition of addiction
2.	Cognitive and psychomotor effects
3.	Incomplete resolution of pain
4.	Physical dependency and episodic withdrawals
5.	Fear of legal/regulatory authorities
6.	Fear of attracting addicts to one's practice
7.	Fear of regulatory authorities (e.g., provincial colleges' restricting licenses)
8.	Misunderstanding of lowered efficacy of opioids in treatment of chronic pain
9.	Fear of development of tolerance; confusion of tolerance with addiction
10.	Additional prescription requirements: Triplicate forms; No refills (schedule-II)
11.	Fear of diversion, abuse, and illicit usage
12.	Cost of sustained-release opioids
13.	Formulary restrictions
14.	Lack of knowledge about opioids, in terms of choices, doses, side effects and withdrawal effects
15.	Inadequate reimbursement for the care of patients with complex conditions causing chronic pain

Sources: (Gardner-Nix, 2003; Gallagher, 2004)

The next section reviews perceived barriers toward prescribing CR opioids for CNMP conditions. A search of the literature was conducted to examine the knowledge, beliefs and attitudes of physicians and other health care professionals toward the use of opioids in treating patients with chronic pain. Information presented will be used to better understand physicians' beliefs toward prescribing CR opioids to CNMP patients.

2.7.1 Fear of Patient Addiction, Physical Dependence and Tolerance

Although effective in treating many types of chronic pain, CR opioids are often used limitedly due to concerns of addiction and abuse and confusion between the concepts (terms) of physical dependence, tolerance, and addiction (Turk *et al.*, 1994; Turk, 1996; Potter *et al.*, 2001; Gourlay *et al.*, 2004; Clark, 2005). A 1973 study revealed that clinicians practice with a considerable amount of misinformation regarding pain management, as well as opioid addiction (Marks& Sachar, 1973). Results from more recent studies continue to demonstrate that physicians may be undereducated in these areas (Marks& Sachar, 1973; Von Roenn *et al.*, 1993; Turk *et al.*, 1994; Von

Gunten& Von Roenn, 1994; Weinstein *et al.*, 2000b; Gilson& Joranson, 2001; Potter *et al.*, 2001). Lack of knowledge and inconsistent use of these terms can lead to physician misunderstanding of the risks associated with using CR opioids for pain. Consequently, patients experiencing moderate to severe CNMP may be under treated and stigmatized for their use of this class of opiate analgesics (Gourlay *et al.*, 2004; Von Roenn *et al.*, 1993).

Since the clinical implications of physical dependence, tolerance, and addiction are managed differently, it is important for physicians to understand standardized definitions used to describe the concepts. A consensus statement developed by the American Academy of Pain Medicine (AAPM), American Pain Society (APS), and American Society of Addiction Medicine (ASAM) established definitions related to the use of opioids (Consensus Document AAPM APS ASAM, 2001). These definitions, are described in Table 2.13. This section will examine some of the more prevalent issues of opioid function in relation to physical dependence, addiction, and tolerance and will review several studies that examined physicians' perceptions of the use of opioids and their effect on patient physical dependence, tolerance, and addiction.

Table 2.13 Definitions Related to the Use of Opioids for the Treatment of Pain

Tolerance A state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time.
Physical dependence A state of adaptation that is manifested by a drug-class-specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.
Addiction A primary, chronic, neurobiological disease characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and/or craving.
Pseudoaddiction A term that has been used to describe patient behaviors that may occur when pain is under treated. It can be distinguished from true addiction in that the behaviors resolve when pain is effectively treated.

Source: (Consensus Document AAPM, APS, ASAM, 2001)

As with any medication that acts on the nervous system, physical dependence can occur and is seen as a state of neuroadaptation characterized by “withdrawal syndrome.” This condition is seen as a normal physiologic phenomenon and should not be confused with the concept of addiction (Otis& Fudin, 2005). It is not uncommon for patients on prolonged opioid therapy to develop physical dependence. Physical dependence is often seen as a problem when opioid doses are not tapered among patients whose pain resolves or if the analgesic is inappropriately withheld (Savage, 1999).

Patients placed on long-term opioid therapy often develop a tolerance to the effects of the analgesic (American Pain Society, 2000). Tolerance to opioids is a natural physiological phenomenon that results in the reduced effect of the analgesic at a consistent dosage over time. The reduced effectiveness of the opioid to relieve pain often requires patients to receive an increased dosage regimen or switch to an alternative opioid analgesic to produce the desired analgesic effect (Baumann, 2002; Otis& Fudin, 2005). Experts recommend patients achieve adequate pain control while receiving consistent opioid doses. Increased pain should be further evaluated for etiology, daily activity, or missed doses. Continued opioid titration is appropriate if no increase in severity of pain occurs, however, if analgesia cannot be achieved without significant side effects, then rotation to alternative opioids may be considered (Gourlay *et al.*, 2004).

Addiction is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving (American Pain Society, 2000; Consensus Document AAPM APS ASAM, 2001). It affects genetically predisposed, biologic and psychosocially vulnerable individuals (Gourlay *et al.*, 2004). Addiction can develop from an interaction of the inherent reinforcing properties (side-effects) of the opioid drug, such as euphoria, diminished perception of negative feelings, and elated psychosocial and physiological experiences (Dickinson *et al.*, 2000). Table 2.14 illustrates some aberrant behaviors associated with addiction. Addiction, unlike physical dependence and tolerance, is not a predictable drug effect.

Table 2.14 Aberrant Drug-Related Behaviors

Behaviors that are less problematic

- Drug hoarding during periods of reduced symptoms
- Acquisition of similar drugs from other medical sources
- Aggressive complaining about the need for higher doses
- Unapproved use of the drug to treat other symptoms
- One or two cases of unsanctioned dose escalation
- Reporting psychic effects not intended by the health care professional
- Requesting specific drugs

Behaviors that are more problematic

- Prescription forgery
- Concurrent abuse of related illicit drugs
- Recurrent prescription losses
- Selling prescription drugs
- Multiple unsanctioned dose escalations
- Stealing or borrowing another patient's drugs
- Obtaining prescription drugs from nonmedical sources

Source:(Gourlay et al., 2004)

Confusion exists among clinicians regarding the risks associated with opioid use and addiction. Factors believed to predispose individual patients are not well understood among many health care providers and no proven method has been established for screening people at risk of addiction (Glajchen, 2001). The prevalence of opioid addiction among patients with CNMP is not clear although previous research suggests that addiction to opioid therapy is relatively uncommon among patients who have no previous history of addiction (Urban *et al.*, 1986; Weissman *et al.*, 1991; Turk, 1996; Glajchen, 2001; Gilron& Bailey, 2003). One study documented only four cases of addiction out of 11,882 patients who were placed on opioid therapy (Porter& Jick, 1980). Another study reported no cases of addiction among the 10,000 patients receiving opioid therapy (Perry& Heidrich, 1982). A more recent survey of opioid use among CNMP patients also revealed little risk of addiction among patients who had no history of abuse (Portenoy, 1994). Conversely, results from other studies suggest addiction to opioids as a considerable risk, particularly among patients with a history of addictive behaviors. Several articles estimate the rate of opioid addiction among these types of patients to be between 3.2 and 18.9 percent (Fishbain *et al.*, 1992; Dickinson *et al.*, 2000; Gilron&

Bailey, 2003). Results from a study examining the use of long-acting opioids for patients with severe, refractive chronic-daily headache observed high addictive behavior among 13 percent of patients (n=7/52) being treated with long-acting CR oxycodone (Robbins& Akbarnia, 2000).

Pseudoaddiction is a more recent term used to describe behaviors that may occur when pain is under treated (Weissman& Haddox, 1989). Pseudoaddiction involves patients who seek additional medications appropriately or inappropriately secondary to significant under treatment of the pain syndrome (Weissman& Haddox, 1989). Unlike addiction, pseudoaddictive behaviors resolve when pain is effectively treated through opioids or other means (Gourlay *et al.*, 2004). This condition occurs among patients who become more focused on obtaining medications and appear to be inappropriately drug seeking. Physicians may misinterpret the drug-seeking for pain relief with aberrant drug-seeking behaviors commonly associated with addicted patients who seek medication for nontherapeutic purposes. Dickson *et al.* (2000) suggest that physicians should recognize CNMP patients who are seeking opioids for inadequate pain relief and understand the behavioral changes that can accompany these types of patients (Dickinson *et al.*, 2000).

As previously discussed, physician understanding of the concepts of physical addiction, dependence, and tolerance may affect their willingness to use CR opioids to treat moderate to severe CNMP. Confusion of these terms, such as labeling a CNMP patient as an addict instead of physically dependent, can contribute to the ongoing confusion in understanding the appropriateness of CR opioids in the treatment of CNMP.

Studies Examining Clinicians' Views on Addiction, Dependence and Tolerance

Several studies have shown that physicians' concerns of addiction, physical dependence, and tolerance may act as barriers to prescribing opioids to patients with CNMP (Coniam, 1989; Weissman *et al.*, 1991; Turk *et al.*, 1994; Turk, 1996; Weinstein *et al.*, 2000a; Potter *et al.*, 2001; Morley-Forster *et al.*, 2003). Some studies contradict this conventional wisdom, showing that physicians have relatively little concern about addiction, dependence, and tolerance with regards to prescribing opioids for CNMP (Turk& Brody, 1992; Turk *et al.*, 1994).

A 1973 study of health practitioners practicing in two New York teaching hospitals reported that physicians practiced with a considerable amount of misinformation on pain management and had mistaken beliefs about opioid addiction (Marks& Sachar, 1973). A questionnaire of 102 hospital physicians found that respondents who exaggerated the dangers of addiction were more likely to prescribe lower dosages of meperidine and subsequently under treat their patients' pain. To determine if patients' pain was being under treated, investigators interviewed hospital inpatients being treated with meperidine and discovered that 32 percent of patients did not reach pain "break-through" and over 40 percent of patients continued to be in moderate distress (Marks& Sachar, 1973).

Since the 1973 study, relatively little has changed with regard to physicians' perceptions and concerns about opioid addiction, tolerance, and physical dependence. In a 1991 survey assessing knowledge and beliefs of 90 Wisconsin physicians on prescribing opioids for chronic pain, 57 percent of survey respondents indicated concerns of patient addiction to the opioids they prescribed. Only 13 percent of respondents indicated concerns of patients' tolerance to opioids (Weissman *et al.*, 1991). A 1992 Joransen *et al*. survey of 304 medical state board members found respondents inaccurately described the concepts of physical dependence and tolerance. Findings revealed that 85 percent of respondents mistakenly described physical dependence as addiction and 41 percent described tolerance as addiction (Joranson *et al.*, 1992). Another 1994 study of Texas physicians found that 41 percent of respondents believed that addiction was a common outcome when prescribing narcotics for chronic pain. Of the 386 respondents surveyed, 28 percent felt that any patient prescribed opioids was at significant risk of addiction. Approximately 40 percent of the physicians indicated that they would be extremely concerned about possible patient addiction if a member of their family was given an opioid (Weinstein *et al.*, 2000).

Concerns of addiction, physical dependence, and tolerance are considered a barrier to prescribing CR opioids for CNMP among primary care physicians (PCPs). A 1997 University of California, San Francisco/Stanford Collaborative Research Network (UCSF/CRN) study examined the beliefs of 161 California primary care physicians

(Potter *et al.*, 2001). Based on the responses to three clinical vignettes (i.e., scenarios for chronic back-pain, post-herpetic neuralgia, and chronic daily headache) presented in Table 2.15, approximately 60 percent of respondents believed that prescribing CR opioids to patients with chronic-daily headache would lead to physical dependence. Whereas, concern for dependence was lower for chronic back pain at 33 percent, and post-herpetic neuralgia at 25 percent. Under the same vignettes, PCPs reported concern about the potential for opioids to cause addiction to chronic-daily headache patients at 74 percent, chronic back pain at 29 percent, and post-herpetic neuralgia at 17 percent. A similar trend was seen for responses to the potential for opioids to cause tolerance, with chronic-daily headache at 49 percent, chronic back pain at 32 percent, and post-herpetic neuralgia at 27 percent. Additional study findings revealed that 35 percent of respondents refused to prescribe long-acting morphine on an "around-the-clock" schedule for CNMP patients due to concerns of addiction, physical dependence and tolerance.

Table 2.15 Results from USCF/CRN Survey of Primary Care Physicians (n=161): Frequency (%) Distribution of Respondents Level of Agreement with Statements Related To 3 Case Vignettes

Statement	Case 1: Chronic Back Pain	Case 2: Post-herpetic Neuralgia	Case 3: Chronic Daily Headache
I could realistically encounter this patient in my practice*	96%	96%	96%
I know how to evaluate and treat this medical condition†	73%	78%	69%
I feel optimistic about helping this patient†	40%	66%	29%
I would refer this patient for further evaluation or treatment*	56%	32%	40%
I would now treat this patient with an opioid*	38%	80%	40%
I would treat with long- acting opioids if the pain persisted†	28%	58%	20%
I would be very concerned about the following complications if I prescribed this patient opioids‡			
Addiction	29%	17%	74%
Diversion for illegal use	3%	1%	37%
Physical dependence	33%	25%	60%
Regulatory scrutiny	9%	7%	23%
Side effects	15%	20%	14%
Tolerance	32%	27%	49%

*These variables were constructed as dichotomous yes/no variables.
†Variables constructed with a 5-point Likert scale. Percentages reflect physicians who either strongly agree or agree with the statement.
‡Variables were constructed with a 3-point scale. Respondents were asked to indicate if they were not concerned, somewhat concerned, or very concerned. The responses reflect those who were very concerned.
Source: (Potter et al., 2001)

Researchers also reported that respondents were less willing to prescribe more potent schedule II opioids for CNMP compared to schedule III opioids. Of the 161 physician respondents, 42 percent indicated they would never prescribe CR opioids (schedule II) to patients with post-herpetic neuralgia, 57 percent would never prescribe them for lower back pain, and 75 percent would never prescribe them for daily headache (Potter *et al.*, 2001).

A 2001 study examining the beliefs of 100 Canadian physicians (70 general practitioners and 30 palliative care practitioners) identified the barriers of addiction as an obstacle to prescribing strong opioids (Morley-Forster *et al.*, 2003). Similar to findings of the UCSF/CRN study, 35 percent of general practitioners (GPs) indicated that they would never use opioids for CNMP, even as a third-line treatment after two previous medications had failed. Further, 40 percent of GP respondents listed addiction as a primary obstacle to prescribing long-acting opioids to patients with CNMP. However, only 30 percent of pain specialty physicians (PSPs) cited addiction as an obstacle. Thirty-one percent of GPs cited the potential for abuse/misuse as another major barrier versus 23 percent of PSPs (Morley-Forster *et al.*, 2003).

A review of the literature found one published study that used a social cognition model to assess the influence of clinician's attitudes toward opioid use for pain. Results from a 2000 survey of 466 Australian registered nurses' (RNs) revealed that their intention to administer opioids to patients was influenced in part by their negative attitudes toward patient addiction (Edwards *et al.*, 2001). The study used the theory of planned behavior (TPB) to predict nurses' intentions to administer opioids to patients in pain (acute and chronic) in the hospital setting. Using a direct attitude scale, researchers found that unfavorable attitudes toward opiate analgesics held among nurse respondents caused them to withhold administration of opioids to patients with chronic pain. Of the respondents, 40 percent indicated that patients with a history of addiction should not be given opioids for their pain. Results also showed that only seven percent of respondents believed opioids to be addictive and 11 percent were unsure if opioids were addictive or not. Overall, a majority of respondents (88%) believed that it would be undesirable for patients to become addicted to opioids (Edwards *et al.*, 2001).

2.7.2 Fear of Regulatory Scrutiny

Concern about regulatory scrutiny is another physician-related barrier believed to affect the prescribing of CR opioids to treat CNMP. Physicians from different specialties report that fear of investigation by state medical boards and drug enforcement agencies regarding their prescribing of strong opioids (e.g., schedule II) affects the way they manage their patients' pain (Gilson& Joranson, 2001). Prescribing what may be considered by regulators as excessive amounts of opioids or prescribing to the wrong type of patient has been shown to negatively influence how physicians handle their chronic pain patients (McIntosh, 1991; Fisher, 2004b). These studies also showed fear of disciplinary action, license revocation and criminal prosecution have been further heightened by sensational media events which spotlight a small number of investigations of physicians charged with excessive prescribing of schedule II and III opioids (McIntosh, 1991; Gilson& Joranson, 2001; Fisher, 2004b).

Studies and discussions by experts have found that a substantial number of physicians express concerns regarding potential disciplinary action against them for prescribing controlled substances to chronic pain patients (McIntosh, 1991; Weissman *et al.*, 1991; Turk& Brody, 1992; Turk *et al.*, 1994; Joranson& Gilson, 1997; Portenoy, 2000). Some of these studies have found that physicians' reluctance to prescribe opioids for CNMP has resulted in ineffective pain relief for large groups of patients (American Pain Society, 2000).

Brief History of Regulatory Scrutiny of Controlled Substances

Over the last decade, pain specialists and patient advocacy groups have brought increased awareness to doctors regarding the under treatment of chronic pain. As a result, several pain management guidelines (refer to Section 2.5) have been developed to assist physicians in using stronger long-acting opioids to treat patients suffering from persistent pain. But as physicians have expanded their use of longer-acting opioids, attention to their prescribing practices by regulatory bodies has also increased. Regulatory investigation by federal and state agencies have become focused on those physicians believed to be prescribing "excessive amounts" of opioids or prescribing to the “wrong type of patient.” Regulatory agencies are profiling physicians who improperly prescribe opioids for the purpose of abuse or profit. These agencies also investigate physicians who are disabled by personal problems with drugs or alcohol, possess dated clinical and therapeutic knowledge, or are duped by various fraudulent patients (Potter *et al.*, 2004).

The actual number of physicians who are investigated by regulatory or state board agencies is relatively low. A 2004 Drug Enforcement Administration (DEA) report showed that a majority of physicians are compliant with medical prescribing laws and appropriately prescribe controlled substances to treat their patients’ medical needs (U.S. Drug Enforcement Administration, 2003). It reported that of the 963,385 physicians registered with DEA in 2003, only 557 investigations were conducted on individuals suspected of violating controlled substances laws. Of those physicians investigated, only 34 physicians were arrested (Table 2.16).

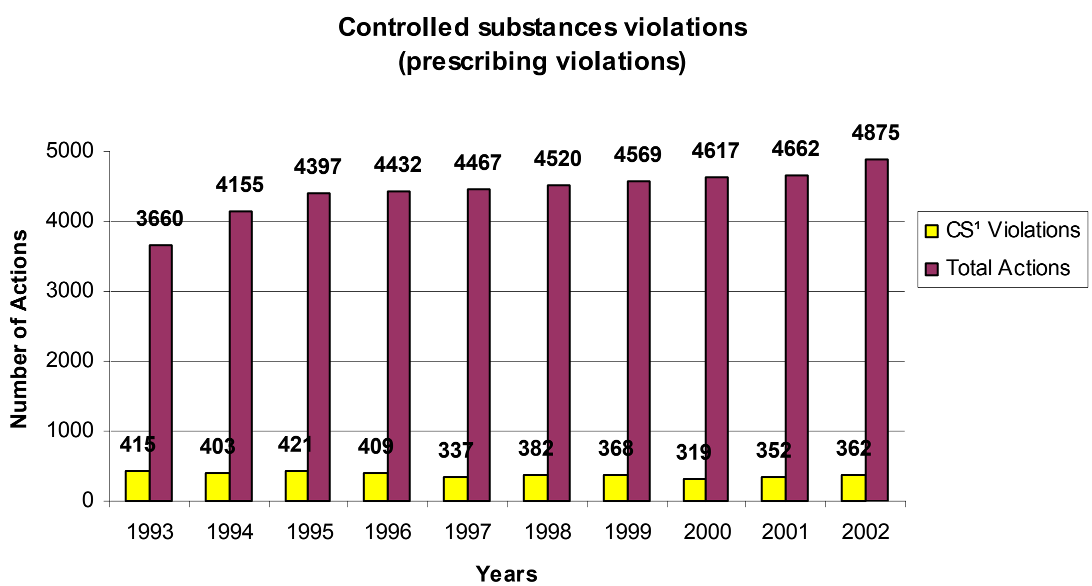
Table 2.16 Investigation of, Actions Taken, and Arrests of Physicians by the Drug Enforcement Agency (DEA) in 2003

	N	% of physician registrants
Total number of physician Registrants	963,385	100%
Investigations of physicians in FY 2003*	557	0.06%
Actions taken against physicians in FY 2003*	441	0.05%
Arrests of physicians in FY 2003*	34	<0.01%

*partial data year- First three quarters of 2003
Source: (Drug enforcement Administration. News from DEA. 2004)

Similar data reported by the Federation of State Medical Boards (FSMB) indicate that less than 10 percent of medical board sanctions imposed on physicians for inappropriate prescribing involved controlled substances (Figure 2.8) (Potter *et al.*, 2004). According to the FSMB report, approximately 1 in 20,000 registered physicians were sanctioned in the U.S. for inappropriate prescribing of controlled substances. Most physicians who were sanctioned were found to be prescribing opioids far outside the scope of legitimate medical practice and were in violation of the law. Yet, cases exist where physicians have been investigated “simply because a large proportion of pain patients in their practice were being prescribed opioids” (Potter *et al.*, 2004). As a result, physicians’ awareness of this increased attention by regulatory and state agencies is believed to adversely affect many physicians’ pain management practices (Gilson& Joranson, 2001).

Figure 2.8 **Controlled Substances Prescribing Violations**



[1]Controlled Substances
Source: Table adapted from Federal State Medical Board, 2004 (Potter *et al.*, 2004)

Federal and State Regulators

Since CR opioids have a potential for abuse, these schedule II drugs are regulated by federal and state controlled substance laws and regulations. The intent of the controlled substance policies are to prevent drug diversion and abuse (Potter *et al.*, 2004). Physicians are given authority through federal and state regulatory agencies (i.e., DEA and state medical boards) to prescribe and dispense “scheduled” substances as long as it is for legitimate medical purposes and follows good medical practice (Angarola& Joranson, 1992; Potter *et al.*, 2004).

The Harrison Narcotic Control Act of 1914, as well as the more recent Controlled Substances Act of 1970 (CSA) were enacted by the federal government to limit the possession and sale of opioids (Brecher, 1972; U.S. Drug Enforcement Administration, 2005). In particular, the more recent CSA was designed to limit the manufacturing and distribution of narcotics, stimulants, depressants, hallucinogens, anabolic steroids, and chemicals used in the illicit production of controlled substances. According to the CSA, all substances regulated under existing law are placed into one of five schedules (categories). These categories are based on the medicinal value, harmfulness, potential for abuse, and addiction of the controlled substance. Schedule I is reserved for the most dangerous drugs that are considered to have no recognized medical use while Schedule V is designated for the least dangerous drugs (U.S. Drug Enforcement Administration, 2005). The most potent analgesics, such as morphine, hydromorphone, oxycodone and fentanyl have been placed in a schedule II category. As a result, CR opioids are considered a schedule II drug.

In a further effort to prevent abuse of CR opioids, many states have imposed greater controls over the medical use of schedule II opioids. These controls include dosage size limitations and the required use of government-issued prescribing forms (duplicate or triplicate prescriptions) (Joranson& Gilson, 1998). In Texas, the adoption of the triplicate prescription system in 1982 required all prescriptions for schedule II drugs to be completed in triplicate forms. Subsequently, an increased use of schedule III medications (e.g., hydrocodone and acetaminophen combinations) for pain control resulted (Berina *et al.*, 1985). Many states have enacted policies that limit the amount of opioids that can be prescribed or dispensed to a patient. Further, 11 states require consultation in specific circumstances when using opioids to treat patients in pain and 10 states have policy provisions that mandate opioids as a therapeutic option of last resort (Pain & Policy Studies Group, 2004).

Over the last two decades, considerable advancement has been achieved in state policy issues involving pain management. The adoption of “intractable pain treatment acts" (IPTAs) by state legislatures has focused on improving clinician pain management practices by specifically permitting the prescribing of opioid medications for chronic pain patients. The primary intention of these statutes has been to address physician concerns of prescribing opioids for the legitimate treatment of chronic pain by providing certain immunities from disciplinary action pursued by the state (Potter *et al.*, 2004). Texas and California were two of the first states to pass intractable pain laws in the late 1980s, authorizing physicians to prescribe opioids for the treatment of pain (Clark& Sees, 1993; Ralston, 1996).

Today, many of the IPTAs adopted by other states are modeled after the 1989 Texas IPTA. To reinforce state pain acts, medical specialty groups and state board agencies have come together to endorse the Model Guidelines for the "Use of Controlled Substances for the Treatment of Pain" (refer to Section 2.5). In a monumental move to "win the war on pain," the Federation of State Medical Boards of the United States, Inc., (FSMB) published the model guidelines for the "Use of Controlled Substances for the Treatment of Pain" (Potter *et al.*, 2004). These policy guidelines were developed to clarify the U.S. state medical board's position on pain control and acknowledge the inadequate management of pain and barriers to appropriate treatment. Endorsed by 24 state boards and 21 health organizations, and recognized by the DEA, the model guidelines were created to reassure physicians that they would not be "disciplined for prescribing opioids to patients with chronic pain if they conform to the standards of 'good clinical practice' and 'state pain policies'" (Potter *et al.*, 2004). The FSMB policy emphasized the need for government and physicians to develop a system that prevents abuse and diversion of controlled substances while ensuring prescribers wide access for legitimate medical use in pain management (Potter *et al.*, 2004). The positive influence of the FSBM guidelines has encouraged state policy makers to recognize the need to encourage more appropriate pain management practices (Potter *et al.*, 2004).

Studies Examining Clinicians' Views on Regulatory Scrutiny

Even though few physicians have been investigated by the DEA or state board agencies, physicians continue to cite fear of regulatory investigation as one of the prominent reasons for not prescribing CR opioids (Fisher, 2004b). Although available research suggests that there is little evidence to support theses concerns (Joranson& Gilson, 1996; Gilson& Joranson, 2001; Potter *et al.*, 2001; Potter *et al.*, 2004), results from several studies suggest that physicians' fear of regulatory scrutiny may act as a barrier to prescribing opioids to patients with CNMP (Coniam, 1989; Weissman *et al.*, 1991; Turk *et al.*, 1994; Turk, 1996; Weinstein *et al.*, 2000a, 2000b; Gilson& Joranson, 2001; Potter *et al.*, 2001; Morley-Forster *et al.*, 2003). Conversely, a few studies found physicians to have relatively low concern about the effects regulatory scrutiny has on their prescribing practices (Weissman *et al.*, 1991; Turk *et al.*, 1994).

Results from the Weissman *et al.* (1991) survey found that only six percent of physician respondents considered regulatory investigation as a primary concern when prescribing opioids (Weissman *et al.*, 1991). Yet, over half of respondents (n=49/90) indicated that they altered their prescribing practice because of fear of regulatory investigation. Researchers found that physician respondents generally had poor knowledge of controlled substance regulations, which caused them to do one of the following: reduce opioid drug dose or quantity, reduce the number of refills, or choose a lower dose schedule (Weissman *et al.*, 1991).

Turk *et al.'s* 1992 national survey found that more family physicians believed that "regulatory pressures" restricted their use of opioids for CNMP compared to respondents from other physician specialty groups (Turk *et al.*, 1994). Though no statistically significant differences were found among respondents with respect to geographic region, investigators did find that physicians' responses to the item differed among groups from states that had legal statutes requiring multiple prescriptions (triplicates) for schedule II drugs. Triplicate states (e.g., California, Michigan and Texas) and non-multiple prescription states (e.g., Washington, Minnesota, and Arizona) were compared. Interestingly, study findings indicated that regulatory pressure was seen to have a smaller effect in states requiring multiple prescriptions versus those states that do not require it ($F_{1,1214}=5.42$, $p<0.003$). ANOVA analyses revealed that physician respondents in triplicate states reported a greater frequency of opioid prescriptions compared to those in non-multiple prescription states ($F_{1, 1225}=12.04$, $p<0.001$) (Turk *et al.*, 1994).

Physician views toward the legality of prescribing opioids for extended periods of time appear to have shifted in the last decade. A 1992 Joransen *et al.* study found nearly half (47%) of respondents believed that prescribing opioids to treat CNMP for extended periods of time should be discouraged. Furthermore, 32 percent of respondents believed extended opioid prescribing violated medical practice laws and should be investigated (Joranson *et al.*, 1992). A 1997 follow-up survey to the Joransen *et al.* (1992) study found a substantial change in regulatory beliefs among medical board members in regards to prescribing opioids for CNMP (Gilson& Joranson, 2001). Fewer respondents (40%) believed that extended opioid prescribing should be discouraged. Only 11 percent of respondents believed this type of prescribing practice violated medical practice laws and should be investigated (Gilson& Joranson, 2001).

Findings from more recent studies appear to be consistent with the results of earlier 1990 studies. The Weinstein *et al.* (2000b) survey of Texas physicians found that one-fourth of respondents believed that prescribing opioids to patients with chronic pain would lead to DEA investigation. Nearly the same number of respondents (24%) believed that if they prescribed a limited supply of pain medications they could avoid regulatory investigation. Approximately 50 percent of respondents believed that too many narcotic prescriptions will lead to utilization reviews but, if they followed the same prescribing practices as other doctors in their field, they would avoid investigation (Weinstein *et al.*, 2000b).

The 2001 Morley-Forster *et al.* survey of Canadian physicians (n =100) found that 17 percent of general practitioners (GPs) indicated regulatory scrutiny as a barrier to prescribing long-acting opioids and 24 percent of GPs indicated that they would use stronger opioids more frequently if not for the perceived threat of sanctions (Morley-Forster *et al.*, 2003). Results from the Ponte and Johnson-Tribino (2005) study found that 68 percent (n=126/185) of family physician respondents indicated that regulatory scrutiny affected their willingness to prescribe opioids.

The Potter *et al*. (2000) study found that 40 percent of physician respondents indicated that fear of legal sanctions limited their use of opioids for CNMP. Results of the survey showed that the level of physicians' concerns of regulatory scrutiny was dependent on the type of CNMP they were treating. Among the PCPs surveyed, 23 percent of respondents indicated they would be "very concerned" of regulatory investigation if they prescribed opioids for chronic daily headache, however only nine percent of the same physicians indicated they would be "very concerned" of regulatory scrutiny if prescribing opioids for chronic back pain and only seven percent would be very concerned for post-herpetic neuralgia (Potter *et al.*, 2001).

The emergence of another dilemma has arisen–the under treatment of pain. Physicians are now at risk of regulatory scrutiny and successfully being sued for under treating patients suffering in pain. In a 1999 case, the Oregon State Medical Board disciplined a physician for failure to adequately treat several of his patients for pain. In 2003, a California physician was successfully sued for under treating a patient's pain. "These cases reflect a changing attitude toward pain treatment in the U.S." (Hoffmann& Tarzian, 2003).

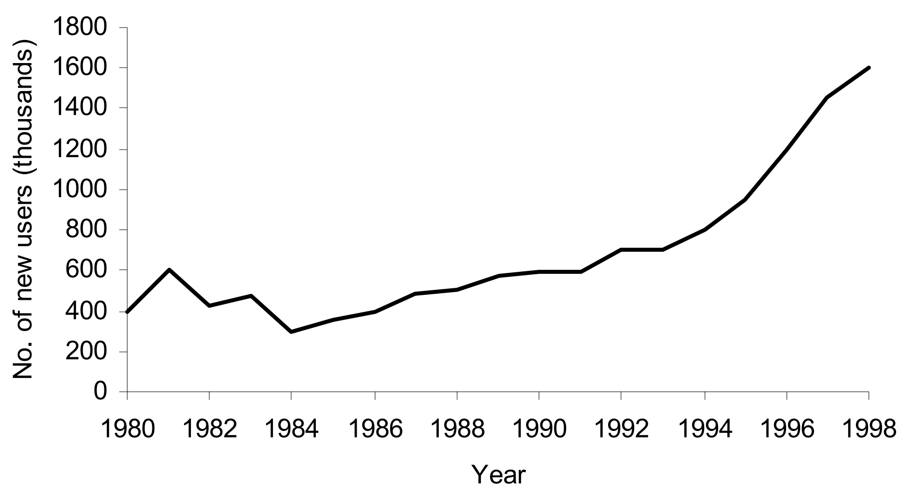
2.7.3 Illicit Usage

Fear of illicit usage (e.g., misuse, abuse and diversion) is another barrier that may affect physicians' prescribing of long-acting opiate analgesics. Misuse is commonly described as any inappropriate use of a pharmaceutical substance that doesn't meet the criteria of addiction. Individuals that misuse opioids often use the medication for non-medicinal purposes to get high or to experience the drugs' euphoric effects (Brookoff, 2000). Abusers may use opioids to medicate symptoms that are not pain-related such as anxiety, depression, insomnia or adjustment problems (Gourlay *et al.*, 2004). While misuse of CR opioids may lead to addiction, depending on the addictive history of the individual, it does not necessarily constitute addiction. Individuals that abuse drugs often exhibit drug seeking behaviors similar to those seen in addicted patients (Savage, 2002).

Most opioids have a street value that makes them a lucrative commodity in the illicit drug market. This is particularly true of CR opioids, which have recently emerged as a major street drug in the U.S. (Collett, 2001; Roth, 2002). As previously discussed in Section 2.4, abusers have learned that they can destroy the controlled-release mechanisms of certain oral forms of long-acting opioids such as CR oxycodone. Crushing and ingesting or diluting this CR opioid in water and injecting it intravenously allows for the full strength of the drug's effects to be felt immediately by the abuser (Roth, 2002). This has caused CR opioids to be highly sought after by illicit drug users.

Prescription opioid abuse is considered a serious and growing problem within the U.S. A 1999 National Household Survey on Drug Abuse (NHSDA) estimated that 1.6 million people used prescription analgesics for non-medical reasons for the first time (Collett, 2001). This is a substantial increase since 1990 when only 564,000 initiates were observed. The 2000 National Survey on Drug Use and Health (formally called the NHSDA) reported that approximately 2 million people in the U.S. aged 12 and older used prescription opioids for non-medical reasons (U.S. Department of Health and Human Services, 2002; Zacny *et al.*, 2003). During that same time period, the NHSDA reported a four-fold increase in prescription opioid abuse rates in the U.S. compared to the 1980s (Figure 2.9).

Figure 2.9 **Number of New Users Taking Prescription Pain Analgesics for Non-medical Uses (1980 -1998)**



Source: adapted from (Substance Abuse and Mental Health Services Administration, 2004)

The wider availability of opioid medications is believed to contribute to the increased illicit trafficking of opioids within the U.S. Novak *et al.* (2004) examined data from the DEA's Automation of Reports and Consolidated Orders System (ARCOS) database and found a substantial increase in the retail distribution of CR opioids like morphine, fentanyl, oxycodone, hydromorphone, and meperidine over the period of 1997 to 2001 (Novak *et al.*, 2004) (Table 2.17).

Table 2.17 Trends in Medical Use of Selected Opiate Analgesics Between 1997 to 2001

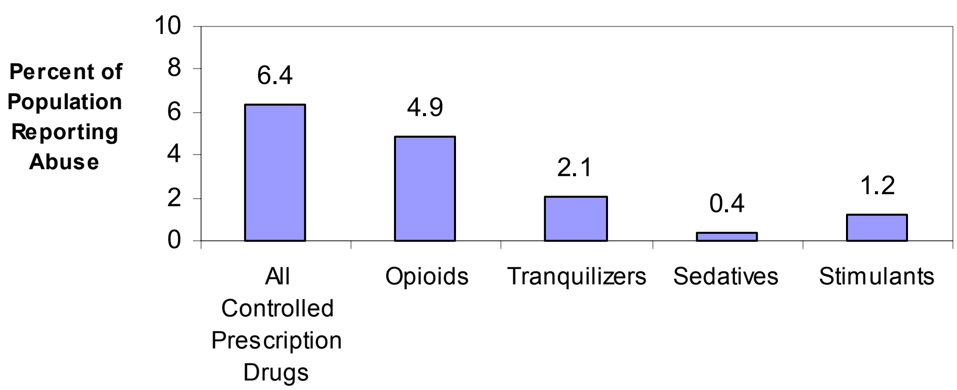
Substances	1997	1998	1999	2000	2001	Percentage change from 1997 to 2001
Fentanyl*	74,085 (27.76)	90,618 (33.96)	107,141 (38.57)	--† --†	186,083 (66.99)	151.18% (141.32%)
Morphine*	5,922,872 (2,219.66)	6,408,322 (2,401.59)	6,804,935 (2,450.02)	--† --†	8,810,700 (3172.17)	48.76% (42.91%)
Oxycodone*	4,449,562 (1667.52)	6,579,719 (2,466.82)	9,717,600 (3,498.69)	15,305,914 (5,510.69)	19,927,287 (7,145.55)	347.85% (328.51%)

* Values are expressed as grams (grams/100,000 population).
† Dash (—) indicates that data are unavailable for this time period.
Source:(Novak et al., 2004)

Though trends in opioid abuse appear to be increasing, the actual level of abuse and adverse events relating to CR opioids remain unclear. A Joranson *et al.* (2000) study found that the trend of increased medical use of opioid analgesics to treat pain between 1990 to 1996 did not appear to contribute to increases in opioid analgesic abuse (Joranson *et al.*, 2000). From their study, the proportion of opioid abuse compared to the total number of reports of all drugs abused decreased from 5.1 percent to 3.8 percent during the 1990 to 1996 period. However, a more recent study conducted by Novak *et al.* (2004), examining abuse of controlled substances between 1997 and 2001, found an increase in opioid abuse. Researchers examined data from the Drug Abuse Warning Network (DAWN) database and found an increase in total opioid analgesic abuse, as evidenced by the total number of drug mentions (from 5.7% to 8.5%) in their analysis of the DAWN database. A large percentage of the increase in mentions was attributed to the CR opioid oxycodone (Novak *et al.*, 2004).

Opioid abuse trends are further substantiated by the 2003 report by the National Center on Addiction and Substance Abuse (CASA) at Columbia University. The report found that the largest group of prescription drug abusers in the U.S. were individuals who abused prescription opioids, comprising 11.4 million people or 4.9% of the U.S. population (Figure 2.10) (National Center on Addiction and Substance Abuse at Columbia University, 2003).

Figure 2.10 **Controlled Prescription Drug Abuse 2003: Report of the National Center on Addiction and Substance Abuse (CASA)**



Source: adapted from Substance Abuse and Mental Health Services Administration Office of Applied Studies (SADAC) (Substance Abuse and Mental Health Services Administration, 2004)

Compared to other illicit drugs, opioid abuse comprised less than 9 percent of drugs misused by illicit drug users (alcohol in-combination at 19%; cocaine at 17%; marijuana at 10%; and other non-opioid drugs at 45%). Official statements from the National Drug Intelligence Center affirms that "the illegal abuse of these [opioids] types of medicinal drugs is the lowest threat among all major drug categories" (National Drug Intelligence Center, 2001). Still, physicians remain cautious when using CR opioids to treat CNMP patients for fear of illicit usage. Physicians are aware that the opioids they prescribe may be abused or diverted by patients. Thus, many physicians may be hesitant in prescribing stronger long-acting opioids to their CNMP patients.

Studies Examining Clinicians' views on Illicit Usage

Findings from several studies have shown mixed responses among physicians regarding patient abuse of opioid analgesics (Gilson& Joranson, 2001; Potter *et al.*, 2001; Hoffmann& Tarzian, 2003; Morley-Forster *et al.*, 2003; Ponte& Johnson-Tribino, 2005). Results from the 1997 Potter *et al.* survey found that physicians' concerns regarding illicit opioid use may be influenced by the type of CNMP the patient may experience (refer to Section 2.7.1, Table 2.15). In their study, more physician respondents indicated that they were very concerned about opioid diversion among patients who had chronic daily headache (37%) compared to those patients who experienced chronic daily back pain (3%) or post herpetic neuralgia (1%) (Potter *et al.*, 2001). When asked about prescribing opioids to patients with a previous history of substance abuse, 16 percent of respondents indicated that they would never prescribe opioids to a patient with previous substance abuse and 42 percent indicated that they would not prescribe opioids to current substance abusers (Potter *et al.*, 2001).

The 2001 Morley-Forester study of Canadian physicians found that 31 percent of general practitioners cited the potential of patient abuse/misuse as being a major obstacle to prescribing long-acting opioids (Morley-Forster *et al.*, 2003). Respondents indicated that a major influence in deciding whether to administer opioids to CNMP patients is based on their history of abuse. Similar results were also seen in the Ponte and Johnson-Tribino study (2005). The survey of West Virginian family physicians found that 92 percent of respondents would not administer opioids to patients with a history of substance abuse (Ponte& Johnson-Tribino, 2005).

State medical regulators had mixed views on the severity of opioid diversion. Findings from the 1997 Gilson and Joranson study indicated that state medical regulators considered opioid diversion to be a minor or moderate problem (Gilson& Joranson, 2001). However, results from the Hoffman and Tarzian (2003) study of 38 state medical board directors, indicated that almost 50 percent of respondents felt drug diversion had become worse in their state while 18 percent felt it had stayed the same. Furthermore, 40 percent felt that the abuse of oxycodone contributed to the trend of illicit opioid diversion (Hoffmann& Tarzian, 2003).

2.7.4 Physician Education

Another barrier to the appropriate prescribing of CR opioids includes insufficient physician education and training in pain management (Otis& Fudin, 2005). Medical educators acknowledge that proper clinical knowledge and positive beliefs toward pain therapy and palliative care can be positively influenced through proper education (Von Roenn *et al.*, 1993). However, though educators recognize the need for improved training in pain management, it is not seen as a priority in medical programs (Benedetti *et al.*, 2001).

Experts agree that physician barriers that result in ineffective CNMP management (e.g., reluctance to prescribing opioids) may originally stem from the low priority pain management is given in medical schools and residency programs (Oneschuk *et al.*, 2000; Benedetti *et al.*, 2001; Glajchen, 2001). Traditionally, medical school curricula have trained physicians to diagnose and treat disease, which commonly is the cause of most pain, rather than treating pain itself (Evans *et al.*, 2003c). Several studies have suggested that physicians' knowledge about the use of opioids in chronic pain management is deficient (Marks& Sachar, 1973; Von Roenn *et al.*, 1993; Turk *et al.*, 1994; Von Gunten& Von Roenn, 1994; Turk, 1996; Weinstein *et al.*, 2000a, 2000b; Gilson& Joranson, 2001; Potter *et al.*, 2001).

Studies Examining Clinicians Views on Education in Pain Management

A Vonn Roenn *et al.* (1993) pain management survey found that 76 percent of physicians surveyed (n=682/897) believed that their limited patient-pain assessment skill was the single most important barrier to adequate pain management. As a result, their reluctance to prescribe opioids may be due, in part, to their limited training, which was cited as the second most important barrier among 61 percent of the respondents. Researchers concluded that proper knowledge in the assessment of pain, the management of side effects, and better understanding of opioid analgesics were needed (Von Roenn *et al.*, 1993). Similar findings were reported in the Turk *et al.* (1994) study where, family physicians felt they had received less than satisfactory education in pain management during medical school and residency (Turk *et al.*, 1994).

Evidence of inadequate education as a barrier in pain management is further supported in Von Grunten and Von Roenn's (1994) study. Results from the 1994 survey revealed that 88 percent of physicians reported their medical school education in pain management was "fair" or "poor" (Von Gunten& Von Roenn, 1994). Further, 73 percent of respondents rated their residency training in pain management as "fair" to "poor." Consequentially, only half of physicians (51%) rated pain management in their own practices as good or very good. Similar responses were observed in the 2002 West Virginia Academy of Family Physicians survey. Of 185 family physicians surveyed, 60 percent of respondents believed that their formal medical training did not prepare them to effectively manage pain (Ponte& Johnson-Tribino, 2005).

Physician continuing education (CE) in pain management should be considered a key strategy in overcoming many of the previously discussed barriers (Oneschuk *et al.*, 2000). In addition to medical school training, post-graduate education activities in pain management may serve as a supplemental training tool to enhance physician knowledge of opiate analgesics and its role in chronic pain management. Research suggests that physicians are more likely to report having accurate knowledge about pain management and opioid analgesics after attending CE courses (Gilson& Joranson, 2001; Gourlay *et al.*, 2004; McCarberg, 2004; Potter *et al.*, 2004; Otis& Fudin, 2005).

Results from the Morley-Forster (2003) study found that most family physician respondents believed that improving their knowledge of pain management could improve their chronic pain treatment practices. Over half of respondents (57%) felt that CE workshops could lead to better educated physicians in pain management (Morley-Forster *et al.*, 2003). Another study found the use of CE training on controlled substances in pain management improved physicians' knowledge and beliefs toward prescribing opioids in CNMP (Gilson& Joranson, 2003). Respondents who attended CE workshops were more likely to view prescribing opioids for CNMP as a lawful and generally acceptable medical practice compared to those who did not attend. Findings showed that at posttest, 75 percent of respondents considered extended opioid prescribing to CNMP patients as legal and medically acceptable to CNMP patients compared to pretest results of 38 percent. The investigators concluded that up-to-date education regarding opioid regulatory policies and opioid pain management could positively affect physician beliefs and lower barriers affecting adequate pain management practices (Gilson& Joranson, 2001).

As previously mentioned, it appears that traditional medical education may not provide physicians with the adequate training needed to effectively manage CNMP patients. Insufficient pain management training in core medical school curricula may allow for negative physician bias toward opioid use in CNMP. Primary care physicians and other health care providers require up-to-date education on topics addressing prevailing treatment options for CNMP. Also, health practitioners need current education to assist them in developing the skills needed to properly evaluate and manage this type of chronic pain among at-risk populations. It is therefore important to examine how post-graduate medical learning (continuing education) may be used to help physicians improve their pain management practices (Sloan *et al.*, 1998).

2.7.5 Other Barriers

Various types of physician-related barriers may affect the appropriate prescribing of CR opioids to treat CNMP patients. As previously discussed, gaps in physician knowledge, negative beliefs toward opioids, inadequate assessment skills, and fear of patient addiction have been recognized as critical obstacles to prescribing opioids.

In addition to those barriers previously discussed, other less-well known physician barriers are believed to influence their prescribing of opiate analgesics for CNMP (Weinstein *et al.*, 2000b; Weisse *et al.*, 2001; Probst *et al.*, 2002; Tamayo-Sarver *et al.*, 2003; Weisse *et al.*, 2003; Goli& Finley, 2005). These barriers can extend to ethnic, racial, gender, and geographic biases which may result in inadequate pain assessment. For example, geographic barriers were observed in the Probst *et al.* (2002) study. Researchers found that rural patients generally had limited access to primary care physicians properly trained in chronic pain management and knowledgeable in the role of opioids in chronic pain therapy (Probst *et al.*, 2002). Compared to urban family physicians, rural family practitioners (who on average see more patients for pain conditions) required additional training in chronic pain syndromes to better meet the needs of their chronic pain patients. Similar findings were also observed in the Weinstein *et al.* (2000) study. In their study, physician respondents practicing in rural areas held more negative views toward opioids, were generally less knowledgeable about pain management, and held more negative views about pain patients than physicians in larger communities (Weinstein *et al.*, 2000).

Physician gender may also play a role in willingness to prescribe opioids to patients with moderate to severe CNMP. Several studies have examined treatment patterns that suggest "possible differences in the treatment approaches of male and female physicians" (Weisse *et al.*, 2001; Weisse *et al.*, 2003; Goli& Finley, 2005). A 2001 survey of 111 primary care physicians examined differences in opioid prescribing practices between male and female physicians (Weisse *et al.*, 2001). Results of the study showed that the rate and dosage of opioids prescribed to chronic pain patients varied between male and female respondents. In a hypothetical scenario of chronic back pain, male physicians indicated that they were more likely to prescribe higher doses of hydrocodone to male patients with chronic back pain than to female patients (406mg vs. 201mg). Similar findings were observed among female physicians prescribing higher doses of hydrocodone to female patients compared to males for the same condition during follow-up (327mg vs. 163mg). Further, male physicians were more likely to prescribe refills of hydrocodone than female physicians for patients with recurrent back pain. ANOVA revealed a significant interaction between physician gender and patient gender ($F_{1,28}$=5.50, P =0.03). Investigators concluded that when treating CNMP, differences in opioid prescribing practices may exist when the role of physician gender was examined (Weisse *et al.*, 2001).

Racial, ethnic and socio-economic disparities may also influence physicians' willingness to prescribe CR opioids for certain CNMP conditions. Several studies have found racial and ethnic differences in physicians' treatment decisions, (Todd *et al.*, 1993;

Ng *et al.*, 1996; Cleeland *et al.*, 1997; Bernabei *et al.*, 1998; Bach *et al.*, 1999; Todd *et al.*, 2000; Stewart *et al.*, 2003), however, some studies have not (Karpman *et al.*, 1997; Tamayo-Sarver *et al.*, 2003). It remains unclear, what role, if any, race or ethnicity plays in opioid treatment decisions. Equally questionable is the degree of influence socio-economic status has on physicians' willingness to prescribe opiate analgesics (van Ryn& Burke, 2000).

Only a handful of studies have shown that physicians prescribe fewer analgesics to minorities compared to majority patients despite their similar estimates of pain (Todd *et al.*, 1993; Todd *et al.*, 2000; Weisse *et al.*, 2001; Weisse *et al.*, 2003). Results from the Weisse *et al.* (2001) study revealed that some physicians were predisposed to different treatment decisions based on patient race/ethnicity. Male physicians were willing to prescribe higher doses of hydrocodone to white patients for chronic back pain compared to black patients (468mg vs. 238mg), while female physicians did the opposite (161mg vs. 335mg). ANOVA revealed a significant interaction between physician gender and patient race ($F_{1,85}$=9.65, P=0.03). Researchers concluded that gender and racial differences may exist and be influenced by the gender and/or racial cues of the patient (Weisse *et al.*, 2001).

2.8 Summary of Literature Review

The adequate treatment of moderate to severe CNMP is a considerable challenge for both the patient and health care provider. The intrinsic sensory, emotional and behavioral components associated with the etiology and severity of CNMP often makes treatment of this type of pain complex. Various pharmacologic and non-pharmacologic options exist to manage patients suffering from moderate to severe CNMP.

Over the last decade, the use of opioids has gained slow acceptance among physicians as an essential component in the management of CNMP when other treatment approaches have failed. Health care experts are beginning to recognize the utility of using longer-acting opioids among a particular subpopulation of patients who experience unremitting CNMP. In fact, many of the more recently published pain management guidelines and evidenced-based studies recommend the use of "sustained release" or "long-acting" opioids to treat a specific group of patients suffering from moderate to severe CNMP (Gardner-Nix, 2003). However, physicians are reluctant to prescribe CR opioids to CNMP patients who may benefit from its long-acting analgesic properties. Their reluctance in prescribing CR opioids may result in inadequate pain management.

Primary care physicians (PCPs) play a critical role in the management of chronic pain among a diverse group of patients. PCPs see more patients than any other specialty (U.S. Department of Health and Human Services, 2005). They are also considered to be on the front-line in providing treatment to patients seeking pain relief. As a result, the successful management of CNMP patients is dependent on the ability of PCPs to understand and utilize effective pain management therapies, including the use of CR opioids.

Numerous studies have attempted to examine the knowledge and beliefs of physicians to better understand the reasoning underlying their treatment behaviors. However, little is known about family physicians' attitudes toward the use of CR opioids for patients suffering from moderate to severe CNMP. This literature review examined some of the issues affecting CNMP and the use of CR opioids in pain management. In particular, the chapter examined some of the issues that are believed to cause physicians to under treat CNMP patients and some of the more prominent barriers believed to affect physicians' willingness to prescribe CR opioids. Some of the physician-related barriers identified included fear of patient addiction, concerns of opioid abuse, regulatory scrutiny, and inadequate education. Factors causing these barriers may be attributed to knowledge deficits or pre-existing beliefs toward opioids or pain. These factors can lead to misconceptions about the role of CR opioids in CNMP. As a result, these factors may act as barriers to the appropriate prescribing of CR opioids for CNMP.

Though some studies were found examining primary care physician beliefs toward opioid prescribing for CNMP, a need exists to better understand how these barriers affect physician beliefs and behavioral intentions. The next chapter will examine the theoretical model that will be used to assess physicians' willingness to prescribe CR opioids for moderate to severe CNMP.

CHAPTER 3: THEORY

3.1 Rationale of Study

The controversy over the use of controlled-release opioids (CR opioids) to treat patients in pain has been extensively discussed in the lay press and scientific literature. Empirical evidence has shown CR opioids to be an effective tool in treating patients suffering from chronic non-malignant pain (CNMP). However, the use of CR opioids to treat CNMP has not been widely accepted among many practitioners. In fact, some physicians are reluctant or unwilling to prescribe CR opioids to treat CNMP patients, even when it is medically appropriate. Concerns of patient addiction, physical dependence, illicit usage, and fear of regulatory scrutiny are some of the factors that may affect physicians' willingness to prescribe CR opioids. Consequentially, these physician-related barriers may result in CNMP patients receiving inadequate pain treatment.

Attitudes toward CR opioids and their role in treating pain may affect physicians' decisions to prescribe this type of opioid for CNMP. In addition to their own attitudes toward prescribing CR opioids, physicians may consider the beliefs of other individuals and groups (e.g., patients, colleagues, staff, family, medical boards) in their decision-making. Further, the level of control physicians have in their prescribing decisions may be influenced by external factors such as formularies, regulatory policies, or utilization management strategies. As a result, it is suspected that these factors play some role in the formation of physicians' intentions (i.e., willingness) to prescribe CR opioids.

A systematic examination of physicians' attitudes and their underlying beliefs toward prescribing CR opioids for CNMP should be explored. No known research has been conducted that specifically examines physicians' beliefs, attitudes, or willingness to prescribe CR opioids to CNMP patients using a grounded theoretical model. This study will contribute to the literature by providing insight into factors perceived to influence physicians' decision-making in prescribing CR opioids to patients with moderate to severe CNMP.

Several models have been used to better understand the intentions and behaviors of health care providers. Models such as the theory of reasoned action and the theory of planned behavior have been used successfully to predict future behavior. Such models could be applied to this study in order to determine physicians' intentions (i.e. willingness) to prescribe long-acting opioids to CNMP patients.

3.2 Theoretical Models to Predict Attitude and Behavior

History

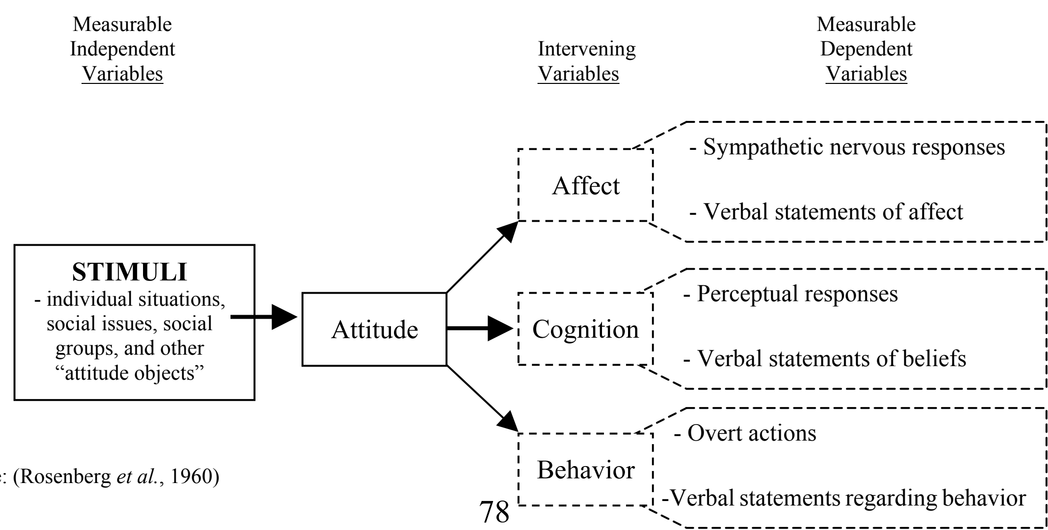
The concept of attitude and its role in explaining behavior first received serious attention in the late 1800s. During this time period, theorists described attitude as a "motor concept" or "physical expression of emotion" (Kantowitz, 1997). Early understanding of the attitude concept posited that various mental or motor states of preparedness influenced people's thoughts or actions (Ajzen& Fishbein, 1980). During the early 1900s, researchers began using the attitude concept to explain social behavior (Thomas& Znaniecki, 1927). Theorists viewed attitudes as individual mental processes that determine a person's actual and potential responses. Theoretical models were designed to measure attitudes as a behavioral predisposition that could be used to explain human action. Much of the early attitude research was descriptive in nature and used to compare attitudes of different segments of the population across a variety of behaviors (e.g., examining attitudes toward prohibition, birth control, voting, race relations and consumer buying habits) (Ajzen& Fishbein, 1980).

Beginning in the 1930s, researchers began a series of debates on the concept of attitude. Many of the discussions focused on identifying the essential components of attitude formation and its relation to behavior. A general consensus held among theorists was that the attitude concept contained an affective (i.e., evaluative) component. However, theorists disagreed on whether beliefs (i.e., cognitions) and behaviors should be included as part of the attitude concept. As the debate persisted over the components of attitude, investigators continued to construct a variety of instruments to assess attitudes across particular domains. The accuracy and validity of these instruments, however, were questionable and this led to a need to develop a valid and standard technique for measuring attitudes (Ajzen& Fishbein, 1980).

Thurstone (1931) introduced the use of pyschometric methods to assist researchers in their assessment of the attitude-behavior relationship (Ajzen& Fishbein, 1980). He developed several different methods to assign scale values to belief statements which measured attitude. These early measurement techniques included the utilization of bipolar adjective scales (e.g., *favorable—unfavorable)* to rate attitude-behavior items. Thurstone's methods enabled researchers to examine belief-based items perceived to be related to the attitude object under consideration (Thurstone, 1931).

Over the next 30 years, researchers continued to develop various models to explain the complex relationship between attitude and behavior. Additional theories were developed to test and explain the direct link between the two concepts. During this time period, attitude-behavior models conceptualized attitudes in the framework of cognition, affect, and conation (Ajzen& Fishbein, 1980). One of the more well-known theoretical models developed during the late 1950s was the multicomponent model (Figure 3.1). This paradigm was used to explain the attitude concept using three components (1) the person's feelings toward the object, (2) the person's beliefs about the object, and (3) the person's action tendencies with respect to the object. Theories, such as this, were used by investigators to explain the attitude-behavior relationship and went unchallenged until the late 1960s (Ajzen& Fishbein, 1980).

Figure 3.1 Multicomponent View of Attitude (Three-component view)



Source: (Rosenberg *et al.*, 1960)

In more recent years, social scientists have shown a growing interest in the relationship between attitudes and behavior (Ajzen& Fishbein, 1980). A re-examination of the attitude concept has led to a growing recognition among investigators that a low empirical relation may exist between attitude and behavior. Some investigators have concluded that attitudes cannot be used to predict behavior. Other researchers have suggested that certain behaviors are dependent on the situational context in which they are observed and are unpredictable from measures of attitude (Ajzen& Fishbein, 1980).

Today, general agreement exists among theorists that attitude is only one of many factors believed to influence behavior (Ajzen& Fishbein, 1980). Investigators have identified additional variables that may contribute to behavioral outcomes. Variables such as personal beliefs, social norms, behavioral intention, self-efficacy, previous experience and demographic characteristics have been linked to behavioral performance (Ajzen& Fishbein, 1980). These variables may be seen as either independent contributors to behavior or as moderators of the attitude-behavior relationship.

Some of the more recent models that have been developed to explain the attitude-behavior relationship include Fishbein and Ajzen's (1975) theory of reasoned action, Ajzen's (1985) theory of planned behavior, and Fazios' (1986) attitude accessibility model. Each theory attempts to predict behavior using the attitude construct with additional predictor variables. In addition, these theoretical models have drawn a clear distinction between an individual's personal beliefs, attitudes, and intentions with respect to behavior (Fishbein& Ajzen, 1975; Ajzen, 1985; Fazio& Williams, 1986).

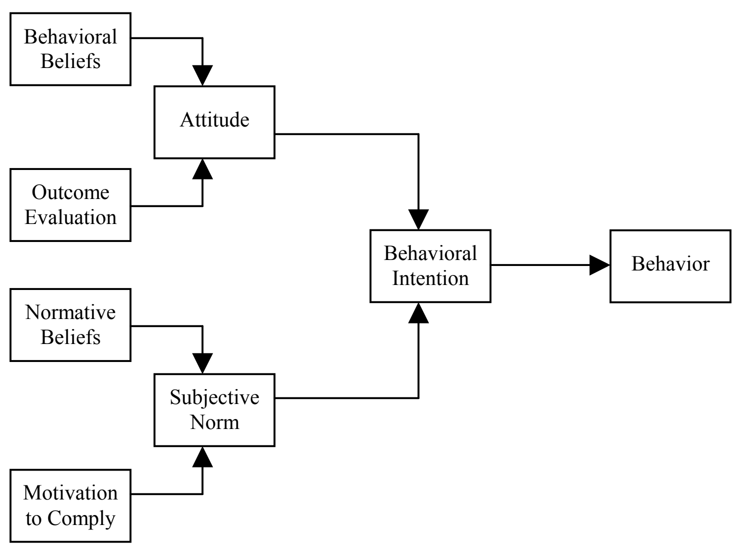
The remainder of this chapter will review two theoretical models: (1) the theory of reasoned action and (2) the theory of planned behavior. Each of the models have been widely used in the literature to predict behavior through the assessment of attitudes and other variables believed to influence intention and behavior. A brief overview will be provided for each of the theories along with an explanation of methodologies used in their assessment. Relevant research studies using the models will also be examined. Finally, the theoretical framework, objectives and hypotheses for this research study will be presented.

3.3 Theory of Reasoned Action (TRA)

Introduced by Martin Fishbein in 1967, the theory of reasoned action (TRA) was originally developed to understand the relationship between attitudes and behaviors (Fishbein, 1967). According to the theory, human action (behavior) is guided by two types of considerations: (1) one's beliefs about the likely outcomes of a particular behavior and the evaluations of those outcomes, and (2) one's beliefs about the normative expectations of others and the motivation to comply with these expectations (Fishbein& Ajzen, 1975).

The TRA reasons that, when dealing with "rational actors," most behaviors can be predicted and explained almost exclusively by intentional beliefs and attitudes (Fishbein& Ajzen, 1975). Furthermore, the model assumes that most actions (i.e., behaviors) of social relevance are under the complete volitional control of the actor and their intention to perform (or not perform) a behavior is the immediate determinant of the action (Ajzen& Fishbein, 1980). It is important to note that unlike prior attitude-behavior models which attempted to explain the relationship of a person's attitude toward an object, the TRA examines a person's attitude toward a behavior with respect to that object (Montano& Kasprzyk, 2002). For example, if investigators were interested in assessing parents' attitudes toward administering specific medications (such as statins) to their child, instead of assessing attitudes toward these medications, the TRA model would examine attitudes toward the behavior of administering these medications to children.

Figure 3.2 Theory of Reasoned Action



Source:(Ajzen& Fishbein, 1980)

TRA Framework

The TRA is comprised of three constructs: (1) behavioral intention, (2) attitude, and (3) subjective norm (Figure 3.2). According to the model, the direct determinants of behavioral intention are the attitude toward performing the behavior of interest and the subjective norm associated with the behavior (Montano& Kasprzyk, 2002). Subsequently, the direct determinant of behavior is behavioral intention. Using a mathematical approach, the theory examines the relationship of the attitude and subjective norm constructs to predict behavioral intention and ultimately behavior.

The following sections will discuss each of the constructs and methods used to assess the direct and indirect measures of the TRA model (Table 3.1)

Table 3.1 Theory of Reasoned Action Constructs and Definitions

Construct	Definition	Measure
1. Behavioral Intention		
a. Direct Measure	Perceived likelihood of performing the behavior	Bipolar scale; e.g., unlikely-likely; scored –3 to +3
2. Attitude		
a. Direct Measure	Overall evaluation of the behavior	Semantic differential scales; e.g.,good-bad,favorable-unfavorable, pleasant-nonpleasant
b. Indirect Measure		
- Behavioral Belief	Belief that behavioral performance is associated with certain attributes or outcomes	Unipolar or bipolar scale; e.g., unlikely-likely scored 1 to 7 or –3 to +3
- Evaluation	Value attached to a behavioral outcome or attribute	Bipolar scale; e.g., bad-good, undesirable-desirable scored –3 to +3
3. Subjective Norm		
a. Direct Measure	Belief about whether most people approve or disapprove of the behavior	Semantic differential scales; e.g., disagree-agree, likely-unlikely, would-would not
b. Indirect Measure		
- Normative Belief	Belief about whether each referent approves or disapproves of the behavior	Bipolar scale; e.g., likely-unlikely; approve-disapprove; scored –3 to +3
- Motivation to comply	Motivation to do what each referent thinks	Unipolar or bipolar scale; e.g., likely-unlikely; scored 1 to 7 or –3 to +3

Source: adapted from (Montano& Kasprzyk, 2002; Francis, 2004)

3.3.1 Attitude

According to the TRA, attitudes are a function of beliefs (Ajzen& Fishbein, 1980). Fishbein and Ajzen (1975) define attitudes as “a learned predisposition to respond in a consistently favorable or unfavorable manner with respect to a given object.” Generally speaking, an attitude toward a concept is simply a person’s feelings of favorableness or unfavorableness toward the concept (Ajzen& Fishbein, 1980). For example, “a person who believes that performing a specific behavior will lead to mostly positive outcomes will hold a favorable attitude toward performing the behavior, while a person who believes that performing the behavior will lead to mostly negative outcomes will hold an unfavorable attitude” (Ajzen& Fishbein, 1980).

The attitude construct has been operationalized as both a global (i.e., direct) and belief-based (i.e., indirect) measure (Fishbein& Ajzen, 1975). Global and belief-based measures are alternate ways of measuring the same construct. Under the TRA, a direct measure of attitude is considered to be the strongest predictor of behavioral intention that leads to the behavior of interest (Montano& Kasprzyk, 2002). However, direct measures are unable to examine the specific personal beliefs that may lead to attitude formation (Fishbein& Ajzen, 1975). Indirect measures are employed to examine specific salient beliefs that may influence attitude formation. Table 3.1 summarizes the direct and indirect measures used for attitude.

It is important to demonstrate that indirect measures are strongly associated with direct measures, in order to establish confidence that the appropriate behavioral beliefs are being measured and that the composite of these beliefs are adequate measures of the TRA construct (Montano& Kasprzyk, 2002). The following sections will discuss each type of attitude measure in more detail.

Direct Measure of Attitudes

Under the TRA framework, a direct measure of attitude can be assessed using questions each made up of a 5-point or 7-point semantic differential scale (refer back to Table 3.1). Direct attitude may be measured using bipolar adjective scales, such as instrumental adjective pairs (e.g., such as, *valuable—worthless*, and *harmful—beneficial*) or experiential adjective scales (e.g., *pleasant—unpleasant*, and *enjoyable—unenjoyable*). These bipolar adjective scales may be taken from a list of published adjective scales that have been shown to load highly on the evaluative factor, across the concepts and populations of interest (Ajzen& Fishbein, 1980; Ajzen, 2002b).

The semantic differential scale is commonly employed to assess attitudes (Ajzen, 2002b). Scaling techniques, such as Likert scaling, Thurston scaling, or Osgood scaling methods, may be used to obtain a respondent's direct attitude. The Osgood semantic scale is recognized as the standard measurement tool used to assess attitudes under the TRA (Osgood *et al.*, 1957; Fishbein& Ajzen, 1975). In this context, the Osgood scale consists of a set of bipolar evaluative adjective scales typically measured using 5-point or 7-point scales.

To illustrate how it is used, consider a hypothetical scenario in which researchers are interested in *understanding parents' attitudes toward administering a statin medication on a daily basis to children with hyperlipidemia (high cholesterol)*. Direct measure items used to assess attitudes could take the following form:

Attitude - Direct measure item

Administering statins on a daily basis to children with hyperlipidemia is

good:	____:	____:	____:	____:	____:	____:	____:	*bad*
	(+3)	(+2)	(+1)	(0)	(-1)	(-2)	(-3)	
harmful:	____:	____:	____:	____:	____:	____:	____:	*beneficial*
	(-3)	(-2)	(-1)	(0)	(+1)	(+2)	(+3)	
pleasant:	____:	____:	____:	____:	____:	____:	____:	*unpleasant*
	(+3)	(+2)	(+1)	(0)	(-1)	(-2)	(-3)	

Summing the scale-items used in this direct measure of attitude results in a single score which represents a person's general evaluation or overall feeling of "favorableness" or "unfavorableness" toward daily administration of statins to hyperlipidemic children.

Indirect Measures of Attitudes

Under the TRA framework, indirect measures of attitude ($\mathbf{A_o}$) are determined by two factors: (1) behavioral beliefs (***b***), and (2) outcome evaluations (***e***) (Fishbein& Ajzen, 1975; Ajzen& Fishbein, 1980). The expectancy-value model uses the equation $\mathbf{A} = \Sigma\, b_i e_i$ to calculate an overall belief-based measure for attitude (Ajzen, 1991).

The first component, ***b*** involves the salient beliefs an individual holds about performing the behavior of interest. Behavioral beliefs are described as "readily available beliefs" that a person holds about the behavior of interest. These salient beliefs may be formed from a person's direct observation, or acquired indirectly by accepting information from outside sources, or self-generated through inference processes (Ajzen& Fishbein, 1980).

Indirect measure items are developed from data gathered through elicitation interviews of the target population. Like direct attitudinal measures, behavioral beliefs are typically measured using a 5-point or 7-point semantic differential scale anchored by bipolar adjective pairs (Osgood *et al.*, 1957; Fishbein& Ajzen, 1975). Behavioral belief measures may be assessed using either a unipolar response scale (1 to 7) or bipolar scale (-3 to +3) (Ajzen, 1991; Francis, 2004). An illustration of a behavioral belief question using a bipolar response scale is presented as follows:

Attitude - Indirect measure item
Behavioral belief (b)

Administering statins on a daily basis to children with hyperlipidemia will cause muscle pain.

extremely unlikely: ____: ____: ____: ____: ____: ____: ____: *extremely likely*
(-3) (-2) (-1) (0) (+1) (+2) (+3)

The second component of the attitude construct, outcome evaluation (***e***), refers to the individual's evaluation of consequences when performing the specific behavior of interest. Considered affective in nature, outcome evaluation is described as the value attached to a behavioral outcome or attribute (Ajzen& Fishbein, 1980). The concept refers to the degree to which a person believes that performing a behavior will result in a "positive" or "negative" outcome and the level to which the outcome is "good" or "bad." Similar to assessing behavioral beliefs, outcome evaluation is measured using a 5-point or 7-point bipolar response scale. An example of an outcome evaluative item using a bipolar response scale is presented as follows:

Attitude – Indirect measure item
Outcome evaluation (e)

Children experiencing muscle pain from daily statin use is

extremely bad: ____: ____: ____: ____: ____: ____: ____: *extremely good*
(-3) (-2) (-1) (0) (+1) (+2) (+3)

Calculating Indirect Measures of Attitudes

Using the expectancy-value model, a person's attitude toward a behavior can be predicted by multiplying his/her behavioral beliefs (***b***) by the evaluation of each consequence to the respective behavior (***e***). Each of the cross-products are then summed to generate an index score (Petty& Cacioppo, 1981). Table 3.2 illustrates how indirect measures would be calculated and interpreted for attitude. Using the hypothetical statin example, a parent was asked to rate the likelihood that daily administration of statins to their hyperlipidemic child would result in the following consequences: (1) lowering child's cholesterol; (2) healthier eating habits; and (3) rhabdomyolysis.

Table 3.2 Determining Attitude (A_o) from b_i and e_i

Consequences of administering statins to children with hyperlipidemia	Belief (b)		Evaluation (e)		Product (b_i) x (e_i)
1. Lowered cholesterol	(+3)	x	(+3)	=	+9
2. Healthier eating habits	(+1)	x	(+3)	=	+3
3. Rhabdomyolysis (i.e., muscle pain)	(+2)	x	(-3)	=	-6
					+6

$$A_B = \sum_{I=1}^{N} e_i b_i = +6$$

Because there are 3 items, the possible range of total scores is (3x ±3) x 3 = - 27 to +27

A_B = Parents' attitude toward prescribing statins to treat children with hyperlipidemia.
b_i = Parents' beliefs have about prescribing statins to treat children with hyperlipidemia.
e_i = Parents' evaluations (assessments) of using statins to treat children with hyperlipidemia.

Interpreting the results from Table 3.2 shows the respondent believes that by administering statins to his/her hyperlipidemic child, lowering cholesterol is extremely likely to occur (+3) and would be an extremely desirable outcome (+3). The second item shows the respondent to slightly believe administering statins will result in healthier eating habits (+1) among children and this would be a highly favorable outcome (+3). For the third item, the respondent moderately believes (+2) that daily statin use will cause muscle pain among children, and he/she feels that this outcome is very undesirable (-3). The overall cross product results in a positive attitude score of +6 for the respondent (possible score range -27 to +27). Therefore, the attitude score of the participant reflects a slightly positive attitude (i.e., in favor of administering statins on a daily basis to hyperlipidemic children).

3.3.2 Subjective Norm

According to the TRA, the second predictor of behavioral intention is subjective norm (refer back to Figure 3.2). Subjective Norm (SN) is the perceived social pressure to engage or not to engage in a specific behavior. It is described by Ajzen and Fishbein, as "a person's belief that most of his or her important others think he/she should or should not perform the behavior in question" (Ajzen& Fishbein, 1980). The TRA recognizes the role social influences play in behavior. The model implies that when forming SN, an individual takes into consideration the normative expectations of other people (e.g., peers, family, friends) when considering to engage or not to engage in a specific behavior (Ajzen& Fishbein, 1980).

Similar to the attitude construct, subjective norms are assessed using direct or indirect measures (refer back to Table 3.1). Indirect items are developed from responses collected from elicitation interviews of the target population. SN items are rated using a 5-point or 7-point semantic differential scale anchored with bipolar adjectives for both direct and indirect measures item pairs such as *disagree—agree, likely—unlikely, should—should not, or not at all—very much.*

Direct measures of Subjective Norm

Ajzen recommends that several item-questions be formulated to obtain a direct measure of subjective norm. Questions constructed should possess both *injunctive* and *descriptive* qualities to enhance the variability associated with each item (Ajzen, 2002b). Examples of injunctive item measures are as follows:

Subjective norm - Direct measure item
Injunctive quality

Most people who are important to me think that

I should not: ____: ____: ____: ____: ____: ____: ____: *I should*
(-3) (-2) (-1) (0) (+1) (+2) (+3)
administer statins on daily basis to my child
with hyperlipidemia.

Subjective norm - Direct measure item
Injunctive quality

If my child has high cholesterol, it is expected of me to administer statins on a daily basis.

extremely unlikely: ____: ____: ____: ____: ____: ____: ____: *extremely likely*
(-3) (-2) (-1) (0) (+1) (+2) (+3)

It should be pointed out that using injunctive items alone may result in low variability for the SN direct measure. This is due, in part, to the likelihood that an individual would perceive that important others would have the same (if not identical) approval of desirable behaviors and similar disapproval of undesirable ones (Ajzen, 2002b). Ajzen recommends that a *descriptive* quality measure be employed to capture descriptive norms (i.e., to determine if important others would perform the behavior in question). Examples of SN direct measure items containing a *descriptive* quality are:

Subjective norm - Direct measure item
Descriptive quality

The people in my life whose opinions I value

would not: ____: ____: ____: ____: ____: ____: ____: *would*
(-3) (-2) (-1) (0) (+1) (+2) (+3)
administer statins on a daily basis to their
child with hyperlipidemia.

Subjective norm - Direct measure item
Descriptive quality

Most people who are important to me would administer statins to their child diagnosed with high cholesterol.

completely false: ____: ____: ____: ____: ____: ____: ____: *completely true*
(-3) (-2) (-1) (0) (+1) (+2) (+3)

Summing the scale-items used in the direct measure of SN results in a single score which represents the level of influence referents have on the individual's behavior.

Indirect measures of Subjective Norm

The indirect measures of the SN construct are determined by two factors: (1) normative beliefs (***n***), and (2) motivation to comply (***m***). The first component, ***n***, involves the individual's perceptions of salient group norms— that is a person's expectations that important individuals or groups (i.e., referents) endorse his/her performing a specific behavior. The second component, ***m***, measures the degree to which an individual is motivated to comply with each of the referents. The expectancy-value model uses the equation $\mathbf{SN} = \Sigma\, n_i m_i$ to calculate an overall belief-based measure for SN (Ajzen, 1991).

Methods used to assess normative beliefs and motivation to comply follow a similar logic to methods used in measuring behavioral beliefs for attitude (Ajzen, 1991). Normative belief measures are assessed using a bipolar rating scale (-3 to +3). However, motivation to comply measures may be assessed using a unipolar (1 to 7) or bipolar response scale (-3 to +3) (Ajzen, 1991; Francis, 2004). Examples of ***n*** and ***m*** item-questions using bipolar rating scales are as follows:

Subjective norm - Indirect measure item
Normative beliefs (n)

My spouse thinks that

I should not: ____: ____: ____: ____: ____: ____: ____: *I should*
(-3) (-2) (-1) (0) (+1) (+2) (+3)
administer statins on daily basis to our child
with hyperlipidemia.

Subjective norm – Indirect measure item
Motivation to comply (m)

Generally speaking, how likely will you do what your spouse thinks
you should do?

not at all: ____: ____: ____: ____: ____: ____: ____: very much
(-3) (-2) (-1) (0) (+1) (+2) (+3)

Calculating Subjective Norm

Table 3.3 illustrates how ***n*** and ***m*** would be calculated and interpreted for subjective norm. Using the statin scenario, elicitation interviews found that members of the target population believed the following referents influenced their decisions to administer statins on a daily basis to a child with hyperlipidemia: (1) spouse, (2) mother, (3) father, (4) physician, and (5) best friend. From the table, the respondent rated how likely (***n***) they believed each referent favored the behavior. The respondent was then asked to rate the likelihood that they would comply (***m***) with the referents' beliefs. The cross-products of ***n*** and ***m*** are summed for a total SN score.

Table 3.3 Determining Subjective Norm (SN) from n_i and m_i

Referents belief of administering statins to children with hyperlipidemia	Normative Belief (n)		Motivation to Comply (m)		Product (n_i) x (m_i)
1. Spouse	(+3)	X	(+3)	=	+9
2. Mother	(-1)	X	(+1)	=	-1
3. Father	(-3)	X	(+1)	=	-3
4. Doctor	(+1)	X	(+3)	=	+3
5. Best friend	(0)	X	(0)	=	0
					+8

$$SN = \sum_{i=1}^{N} n_i m_i = +8$$

Because there are 5 items, the possible range of total scores is (±3 x 3)x 5 = -45 to +45

SN = Respondent's subjective norm about administering statins to treat children with hyperlipidemia.
$\mathbf{n}_i$ = Respondent's normative beliefs about administering statins to treat children with hyperlipidemia.
$\mathbf{m}_i$ = Respondent's motivation to comply with referents' beliefs.

Interpretation of Table 3.3 shows that the respondent believes that it is extremely likely (+3) that his/her spouse would approve of him/her administering statins on daily basis to children; and the respondent is extremely likely (+3) to comply with what the spouse would want him/her to do. On the other hand, the respondent believes that it is extremely unlikely that his/her father would approve of the behavior (-3) and he/she would be somewhat likely to comply (+1) with his/her father. Similar interpretations can be observed for other referents listed in the table. Overall, the respondent shows a slightly favorable subjective norm score of +8 (possible range -45 to +45), indicating a weak positive social support to administer statins to a hyperlipidemic child.

3.3.3 Behavioral Intention

Defined by Fishbein and Ajzen, behavioral intention is "a measure of the likelihood that a person will engage in a given behavior" (Ajzen& Fishbein, 1980). According to the TRA, behavioral intention (intention) is the immediate determinant of behavior. Intention is specified as a person's readiness to perform a given behavior and is based on one's attitude toward the target behavior and subjective norm with respect to the target. The TRA makes the assumption that most actions of social relevance are under the volitional control of an individual. The intention to perform the action of interest is seen to be an immediate antecedent of the behavior itself. Equation 3.1 presents the full TRA model relating behavioral intentions to attitudes and subjective norms. Equation 3.2 presents the short form of the equation.

Equations 3.1 Behavioral Intention Formation

$$I = w_1 \left[\sum_{i=1}^{N} b_i e_i \right] + w_2 \left[\sum_{i=1}^{N} n_i m_i \right]$$

Equation 3.2 (short form)

$$I = (w_1)(A_B) + (w_2)(SN)$$

I = behavioral intention
w = weights
b_i = belief about object's attributes or about act's consequences
e_i = evaluations of attributes or consequences
n_i = normative beliefs (strength)
m_i = motivation to comply (with the referent)

A_B = attitude toward object, issue, etc.
SN = subjective norm toward the object

Note: i refers to the specific belief number where beliefs are numbered 1 to N
Source: (Petty& Cacioppo, 1981)

Direct Measure of Behavioral Intention

Behavioral intention is assessed using global (direct) measures. Intention is measured using a 5-point or 7-point semantic differential scale. Measurement scales consist of bipolar adjective pairs anchored at –3 and +3. Bipolar adjective pairs include terms such as *unlikely—likely*, *true—untrue,* or *disagree—agree* (Ajzen, 2002b). Examples of the intention direct measure items are as follows:

Behavioral Intention - Direct measure item

I intend to administer statins on a daily basis to my child diagnosed with high cholesterol.

extremely unlikely: ____: ____: ____: ____: ____: ____: ____: *extremely likely*
(-3) (-2) (-1) (0) (+1) (+2) (+3)

Behavioral Intention - Direct measure item

I will try to administer statins on a daily basis to my child diagnosed with high cholesterol.

definitely false: ____: ____: ____: ____: ____: ____: ____: *definitely true*
(-3) (-2) (-1) (0) (+1) (+2) (+3)

Calculating Behavioral Intentions

Only direct measures are assessed for behavioral intention. As a result, direct measure items for each respondent are summed and averaged to create an index score. Regression analyses (calculations illustrated in Equation 3.1 and 3.2) were conducted to determine the utility of the theoretical model in explaining physicians' intentions (i.e., willingness).

3.3.4 Studies Using the TRA

The TRA has been used in numerous studies to examine a variety of social behaviors (Petty& Cacioppo, 1981). The theory has been used to predict and explain numerous health behaviors and intentions including smoking, drinking, contraceptive use, mammography screening, use of health care services, exercise, seat belt use, safety helmet use, sun protection, breastfeeding, HIV prevention, sexually transmitted disease prevention and substance use behaviors (Montano& Kasprzyk, 2002).

Empirical research has established the utility of the TRA in predicting various types of behaviors considered to be under volitional control. A meta-analysis conducted by Shepperd *et al.* (1988) investigated the utility of the TRA and found the model to be an overall good predictor of intention and behavior (I-B). Researchers used 87 studies to investigate the I-B relationship and 87 separate studies to examine the attitude, subjective norm and intention relationship (A_o+SN-I). Studies used in the meta-analysis explored 174 behaviors including voting, exercise, work absenteeism, vaccination, birth control, smoking, dating, dieting, alcohol consumption, and prescription drug use. Based on results of their meta-analysis, investigators found a relatively strong correlation of $R=0.53$ ($p=0.01$) for the I-B relationship and a strong correlation of $R=0.66$ ($p=0.001$) for A_o+SN-I. Findings indicated that the 28 percent of the variance in behavior was due to intentions and 44 percent of the variance in intentions was owed to A_o+SN. Though the results of the meta-analysis showed support for the TRA, investigators did indicate that only 17 studies used the model correctly to examine the I-B relationship and only 10 studies examined the A_o+SN-I relationship as the model was originally intended. Sheppard *et al.* found that some studies were either measuring goals instead of behaviors (e.g., losing 10 pounds vs. taking a diet pill), measuring more than one behavior, providing alternative choices to respondents or measuring respondents estimation of performing the target behavior (instead of intention). Nonetheless, the TRA model was shown to perform generally well among these studies and investigators demonstrated strong support for the predictive utility of the model (Sheppard *et al.*, 1988).

A 2002 meta-analysis, conducted by Haggar *et al*., further supports the efficiency of the TRA (Hagger *et al.*, 2002). Investigators reviewed 72 TRA studies to assess the I-B and A_o+SN-I relationships. Studies reviewed in the meta-analysis involved assessing exercise and leisure behaviors. Using path analysis, relationships between behavior, behavioral intentions, attitudes, subjective norms and several other predictor variables were explored. Under the TRA, investigators found intention to be a "good" predictor of behavior. Results showed that intentions significantly predicted behavior ($\beta=0.51$, $p<0.01$). Attitudes were also seen as a significant predictor of intention ($\beta=0.56$, $p<0.01$) and subjective norms had a small but significant influence on intentions ($\beta=0.12, p<0.01$).

Overall, the TRA constructs explained approximately 37 percent of the variance in intentions (A_o+SN-I) and 26 percent of the variance in behavior (I-B) (Hagger *et al.*, 2002).

As shown above, a review of the literature found the TRA model to be an adequate predictor of various health behaviors under volitional control. However, relatively few studies have used the TRA to examine physician behaviors (Millstein, 1996; Lambert *et al.*, 1997).

TRA Physician Studies

The Millstein (1996) study found the TRA model to be an adequate predictor of physician intentions and behavior. A pretest-posttest survey of 765 California primary care physicians was conducted to examine the utility of the TRA (and theory of planned behavior) for predicting physicians' delivery of preventative services (i.e., educating adolescent patients about sexually transmitted diseases). Two separate surveys were administered to participants six months apart. Pretest data (Time 1) were used to analyze the A_o+SN-I relationship and posttest data (Time 2) were used to analyze the I-B relationship. Results for Time 1 data showed that regressing intention on the attitude and subjective norm constructs yielded a significant overall model ($R=0.39$, $p<0.0001$), accounting for 15 percent of the variance in intention. The TRA model yielded significant beta weights for attitudes ($\beta=0.22$, $p<0.0001$) and subjective norms ($\beta=0.28$, $p<0.0001$). Results for Time 2 showed attitude ($\beta=0.26$, $p<0.0001$) and subjective norm ($\beta=0.15$ $p<0.0001$) to be significantly associated with subsequent behavior. Intention was also observed to have a significant relationship with behavior ($\beta=0.56$, $p<0.0001$). Overall, the TRA model accounted for 27 percent of the variance in behavior ($R=0.61$, $p<0.0001$). Study findings also confirmed the importance of social normative beliefs in influencing physician behavior. Millstein concluded that though the TRA was able to predict the indirect effects of attitudes and subjective norms on behavior, study findings may be applicable only to behaviors that are perceived to be under complete volitional control (Millstein, 1996). As a result, the model may not be appropriate in predicting certain behaviors that are not under complete volitional control of the physician.

A study conducted by Lambert *et al.* (1997) found the TRA to be a poor predictor of physician prescribing behavior. In a cross-sectional study of 25 managed care physicians, investigators used the TRA model to examine attitudinal and social normative factors believed to influence the prescribing of seven antibiotics listed within a U.S. managed care formulary (Lambert *et al.*, 1997). Results of correlational and multiple regression analyses found intention to be significantly associated with attitude and subjective norm ($p<0.05$). Data showed a significant correlation between direct measures of attitude and intention for each of the seven antibiotics (r values ranged from 0.41 to 0.74, $p<0.05$). Direct measures of subjective norm and intention were also significantly correlated (r values ranged from 0.53 to 0.88, $p<0.01$). However, physician prescribing intentions were not significantly correlated with actual antibiotic prescribing behaviors. Lambert *et al*. concluded the A_o+SN-I constructs were poor predictors of actual antibiotic prescribing behavior. It was interesting to note that, similar to the Millstein (1996) study, social norms exerted a stronger influence on prescribing intentions than did attitudinal considerations for this study. Investigators posited that physician prescribing behaviors were more strongly influenced by what others thought (e.g., managed care, staff) than by their own beliefs or attitudes. Some of the more prominent limitations addressed by investigators included small sample size, physicians' response bias to provide socially desirable answers, and the assumption that physicians had complete volitional control in prescribing behavior (Lambert *et al.*, 1997).

Limitations of TRA

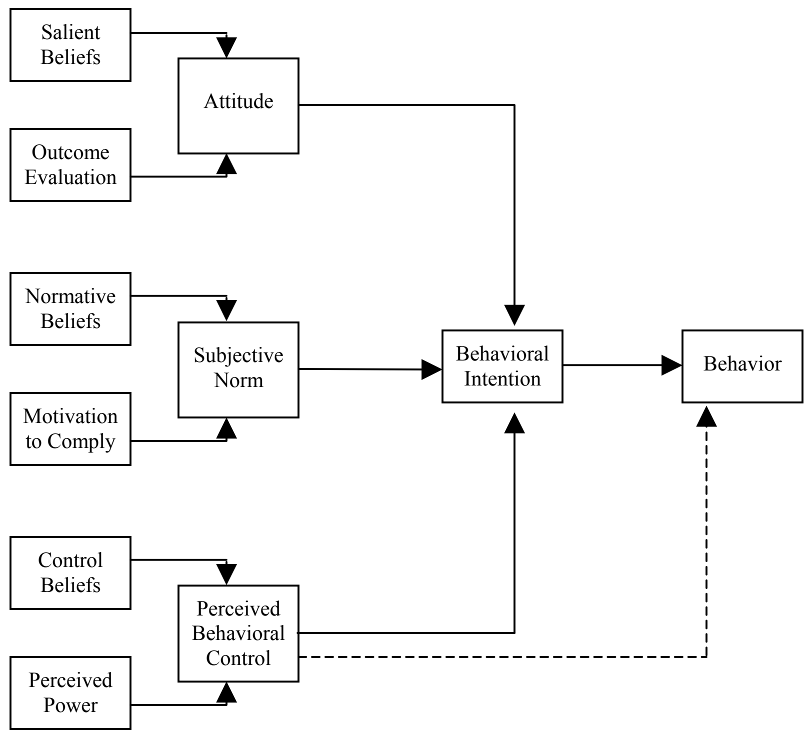
Though the TRA provides a well-defined framework to examine the attitude, subjective norm, and behavioral intention constructs, it does have several limitations. The following include, but are not limited to, some of the more common limitations of the TRA. The most important limitation is that the TRA can only predict behaviors that are under complete volitional control (Ajzen, 1991; Montano& Kasprzyk, 2002). As a result, the model is not appropriate for assessing behaviors that are not under complete volitional control of the individual being examined. Another limitation is that the theory is applicable to individuals who are considered "rational actors." These individuals must be able to cognitively process information and are motivated to act on it (Fishbein& Ajzen, 1975). A third limitation is the model's reduced predictive ability for cross-sectional studies. Applying the model to cross-sectional studies may result in poorer prediction of previous behavior, particularly if the respondents' intentions or beliefs change over time (Ajzen& Fishbein, 1980; Montano& Kasprzyk, 2002). Finally, poorly conducted elicitation interviews and selection bias (e.g., focus group participants) may result in inadequate identification of underlying outcomes and social influence (i.e., referents) which could lead to poorly constructed TRA measures and subsequent inadequate behavioral prediction (Montano& Kasprzyk, 2002; Ajzen& Fishbein, 2004).

Recognizing the limitations of the TRA, specifically the model's inability to confidently predict behaviors that are not under complete volitional control, researchers developed the Theory of Planned Behavior (TPB) to assess non-volitional actions (Ajzen& Madden, 1986; Ajzen, 1991; Ajzen& Driver, 1992). Originally developed by Ajzen (1985), the revised theory incorporates an additional construct to the model to assess the individual's perceived control over the behavior of interest. The next section discusses the TPB and its application in predicting behaviors that are not under complete volitional control.

3.4 Theory of Planned Behavior (TPB)

The Theory of Planned Behavior (TPB) is an extension of the theory of reasoned action (Ajzen, 1985). Developed by Ajzen and colleagues, the TPB attempts to predict behaviors over which people do not have complete volitional control (Ajzen& Madden, 1986; Ajzen, 1991; Ajzen& Driver, 1992). The theory postulates three conceptually independent determinants of behavioral intention (Figure 3.3). Similar to the TRA model, the first two determinants of behavioral intention are attitude (A_o) toward the behavior and subjective norm (SN). The third predictor relates to the degree of perceived behavioral control (PBC) an individual has over performing the target behavior.

Figure 3.3 Theory of Planned Behavior



Source:(Ajzen, 1991)

The TPB model also posits that PBC may be used to directly predict behavior. Ajzen provides two rationales for the direct relationship (Ajzen, 1991). First, holding behavioral intention constant, it is reasoned that efforts used to bring a behavior to a successful conclusion will increase as PBC increases. For example, an individual who is more confident in performing a target behavior will be more likely to persevere in performing the behavior compared to an individual who doubts his ability. Second, PBC may be used as a substitute measure for actual behavior when individuals who have high levels of PBC also successfully perform the behavior of interest (Ajzen, 1991). The following sections will discuss the PBC construct and methods used to assess the direct and indirect measures of the TPB model (Table 3.4).

Table 3.4 Theory of Planned Behavior Constructs and Definitions

Construct	Definition	Measure
1. Behavioral Intention		
a. Direct Measure	Perceived likelihood of performing the behavior	Bipolar scale; e.g., unlikely-likely; scored –3 to +3
2. Attitude		
a. Direct Measure	Overall evaluation of the behavior	Semantic differential scales; e.g.,good-bad; favorable-unfavorable, pleasant-nonpleasant
b. Indirect Measure		
- Behavioral Belief	Belief that behavioral performance is associated with certain attributes or outcomes	Unipolar or bipolar scale; e.g., unlikely-likely scored 1 to 7 or –3 to +3
- Evaluation	Value attached to a behavioral outcome or attribute	Bipolar scale; e.g., bad-good, undesirable-desirable scored –3 to +3
3. Subjective Norm		
a. Direct Measure	Belief about whether most people approve or disapprove of the behavior	Semantic differential scales; e.g., disagree-agree, likely-unlikely, would-would not
b. Indirect Measure		
- Normative Belief	Belief about whether each referent approves or disapproves of the behavior	Bipolar scale; e.g., likely-unlikely; approve-disapprove; scored –3 to +3
- Motivation to comply	Motivation to do what each referent thinks	Unipolar or bipolar scale; e.g., likely-unlikely; scored 1 to 7 or –3 to +3
4. Perceived Behavioral Control		
a. Direct Measure	Overall measure of perceived control over the behavior	Semantic differential scales: e.g., up to me-not up to me, difficult-easy, disagree-agree
b. Indirect Measure		
- Control belief	Perceived likelihood of occurrence of each facilitating or constraining condition	Unipolar or bipolar scale; e.g., unlikely-likely, difficult-easy; scored 1 to 7 or –3 to +3
- Perceived power	Perceived effect of each condition in making behavioral performance difficult or easy	Bipolar scale; e.g., difficult-easy, no control-complete control; scored -3 to +3

Source: adapted from (Montano& Kasprzyk, 2002; Francis, 2004)

3.4.1 Perceived Behavioral Control

Ajzen and colleagues describe Perceived Behavioral Control (PBC) as "a person's beliefs as to how easy or difficult the performance of a behavior is likely to be [when] beliefs about resources and opportunities may be viewed as underlying perceived control" (Ajzen& Madden, 1986). PBC was added to the original TRA model in an effort to account for those factors considered outside an individual's control, that may influence his/her intention or behavior (Montano& Kasprzyk, 2002). This extension was based on the rationale that a person's action (behavioral performance) is determined by his/her motivation (intention) and ability (behavioral control). Ajzen argues that "a person will expend more effort to perform a behavior when his/her perception of behavioral control is high" (Montano& Kasprzyk, 2002). For example, if a person holds strong control beliefs regarding the existence of specific factors that will facilitate a specific behavior, then he is considered to have a high level of PBC over the target behavior. On the other hand, if a person holds strong control beliefs about the existence of specific factors that will impede his behavior, then he is considered to have a low level of PBC over the target behavior (Ajzen, 1991).

Under the TPB framework, PBC together with intention may be used to directly predict behavior. Ajzen (1991) argues that an individual who perceives that he/she has high control over a specific behavior will expend more effort to perform the action of interest. The rationale for this assumption is that behavioral performance is determined jointly by motivation (intention) and ability (behavioral control) (Montano& Kasprzyk, 2002).

The PBC construct is similar to Bandura's construct of self-efficacy and Triandis's conceptualization of facilitating conditions (Triandis, 1980; Bandura, 1991). Ajzen combined the notions of self-efficacy and perceived control to create the PBC construct which is considered to be a more suitable predictor of behavior for the TPB model (Edwards *et al.*, 2001).

Perceived behavioral control is operationalized as either a global or belief-based measure (Notani, 1998). Table 3.4 (previous table) provides a summary of direct and indirect measures for this construct. PBC items are constructed from data gathered through elicitation interviews conducted among the target population. Both direct and indirect PBC items are rated using a 5-point to 7-point bipolar or unipolar scale. Belief-based measures are calculated using the expectancy-value model (Ajzen, 1991; Ajzen, 2002b).

Direct Measures of Perceived Behavioral Control

Global measures of PBC are designed to measure an individual's overall confidence in his/her capabilities to carry out the behavior of interest (Ajzen, 2002b). A PBC direct measure generally consists of two to four question-items (Notani, 1998). Ajzen suggests using two types of direct measure items: (1) *self-efficacy*, and (2) *controllability* (Ajzen, 2002b). First, self-efficacy items are used to measure an individual's perceived level of difficulty in performing the specific behavior. Bipolar adjective items for the scale can include *difficult—easy* or *up to me—not up to me.* Examples of self-efficacy items are as follows:

Perceived Behavioral Control - Direct measure item
Self-efficacy

For me to administer statins on a daily basis to my hyperlipidemic child would be

very difficult: ____: ____: ____: ____: ____: ____: ____: *very easy*
(-3) (-2) (-1) (0) (+1) (+2) (+3)

Perceived Behavioral Control - Direct measure item
Self-efficacy

If I wanted to, I could administer statins on a daily basis to my hyperlipidemic child.

strongly disagree: ____: ____: ____: ____: ____: ____: ____: *strongly agree*
(-3) (-2) (-1) (0) (+1) (+2) (+3)

Second, controllability items are used to assess the level of control a person believes he/she has over the target behavior. This type of global measure examines the degree to which an individual believes the performance of the target behavior is up to him/her. The following examples illustrate this type of direct measure items:

Perceived Behavioral Control - Direct measure item
Controllability

How much control do you believe you have over administering statins on daily basis to your hyperlipidemic child?

no control: ____: ____: ____: ____: ____: ____: ____: *complete control*
(-3) (-2) (-1) (0) (+1) (+2) (+3)

Perceived Behavioral Control - Direct measure item
Controllability

It is mostly up to me whether or not I administer statins on a daily basis to my child diagnosed with high cholesterol.

strongly disagree: ____: ____: ____: ____: ____: ____: *strongly agree*
____:
(-3) (-2) (-1) (0) (+1) (+2) (+3)

Ajzen suggests using both self-efficacy and controllability item scales to assess direct measure items for PBC. He further points out that direct measure scales be developed so that each set of items used has a high degree of internal consistency (Ajzen, 2002b).

Indirect Measures of Perceived Behavioral Control

The indirect measure of PBC is determined by two variables: (1) control belief (***c***) and (2) perceived power (***p***). The first variable, ***c,*** is described as a salient belief an individual holds concerning the existence of specific factors which may facilitate or impede behavioral performance. The second variable, ***p,*** involves the level of perceived power (i.e., impact) each factor has on facilitating or impeding the target behavior (Montano& Kasprzyk, 2002). The expectancy-value model uses the equation $\mathbf{PBC = \Sigma}\ \boldsymbol{cp}$ to calculate an overall belief-based measure of perceived behavioral control (Ajzen, 1991).

Similar to procedures used for attitude and subjective norm, control beliefs are identified through elicitation interviews. Once salient control beliefs are identified, Ajzen suggests using a 7-point semantic differential scale to measure indirect items (Ajzen, 2002b). Control beliefs and perceived power may be measured using a either unipolar (1 to 7) or bipolar (-3 to +3) response scale (Ajzen, 1991; Francis, 2004).

Examples of indirect PBC questions-items are as follows:

Perceived behavioral control - Indirect measure item
Control belief strength (c)

I expect that my child will be able to swallow his/her statin medication.

highly unlikely: ____: ____: ____: ____: ____: ____: ____: *highly likely*
(-3) (-2) (-1) (0) (+1) (+2) (+3)

Perceived behavioral control - Indirect measure item
Perceived power (p)

I feel that I have no control/complete control over getting my child to swallow his/her statin medication on daily basis

no control : ____: ____: ____: ____: ____: ____: ____: *complete control*
(1) (2) (3) (4) (5) (6) (7)

Calculating Perceived Behavioral Control

Table 3.5 illustrates how control beliefs and perceived power would be calculated and interpreted for PBC. Using the statin scenario, three salient control beliefs that are believed to affect a parent's perceived control in administering statins are: (1) the child's inability to swallow a statin pill, (2) access to transportation to pick up medication from the pharmacy, and (3) the ability to soothe muscle soreness (i.e., rhabdomyolysis). The respondent will rate the likelihood of encountering each of the factors (***c***), and the level/degree to which they perceived each factor (***p***) would make it easier or difficult to administer statins to his/her child.

Table 3.5	**Perceived Behavioral Control (PBC) from c_i and p_i**				
Perceived control over the daily administration of statins to a child with hyperlipidemia.	Control belief (c)		Perceive power (p)		Product (c_i) x (p_i)
1. Child's inability to swallow pills	(-3)	x	(+2)	=	-6
2. Access to transportation to pick up medication from pharmacy	(+3)	x	(+1)	=	+3
3. Inability to soothe child's muscle soreness resulting from statin use	(-3)	x	(+2)	=	-6
					-9

$$PBC = \sum_{i=1}^{N} c_i p_i = -9$$

Because there are 3 items, the possible range of total scores is (3x ±7) x 3 = - 63 to +63

PBC = Respondent's perceived behavioral control about administering statins to treat children with hyperlipidemia
c_i = Respondent's control beliefs about administering statins to treat children with hyperlipidemia
p_i = Respondent's perceived power over administering statins to treat children with hyperlipidemia

Results from Table 3.5 show that the respondent believes that the inability for a child to swallow a statin pill would make it extremely difficult (-3) to administer the medication. In addition, the respondent feels he/she would have slight power in getting their child to swallow his/her medication (+2) under the this condition. For the transportation item, the respondent believes access to transportation to make it extremely easy (+3) to administer statins, however he/she feels they have no power in getting transportation (+1) to pick up the child's medication from the pharmacy. For the third item, the respondent indicates that it is extremely likely (+3) that his/her child encounter muscle soreness while taking statins and the respondent believes that they he/she will have little power (-2) in relieving the muscle soreness. The summed cross product for all items results in a negative score for PBC (-9). Therefore, the score of the participant reflects a weak level of negative control (i.e., administering statins on a daily basis to a hyperlipidemic child will be slightly difficult).

3.4.2 Studies Using TPB

More researchers are using the Theory of Planned Behavior (TPB) to explain a variety of behaviors that are considered not under complete volitional control. Empirical research has examined the TPBs utility for non-volitional behaviors such as alcohol and caffeine consumption, eating, exercising, gift-giving, health screening, oral hygiene, weight loss, shopping, sleeping, taking vitamins, and others (Madden *et al.*, 1992; Notani, 1998; Armitage& Conner, 2001; Hagger *et al.*, 2002). Most studies investigating the efficacy of the TPB generally examine the perceived behavioral control (PBC) construct. A 1992 study conducted by Madden *et al*. compared the efficiency of the TPB to the Theory of Reasoned Action (TRA) (Madden *et al.*, 1992). They examined 10 different types of domestic behaviors (such as, sleeping, shopping, exercising, washing the car, talking to friends, doing laundry, consuming caffeine, renting videocassettes, buying albums and taking vitamins) among a group of 94 college students. Results indicted that the TPB constructs increased the prediction of behavioral intention from 48 percent for the TRA model to 59 percent for the TPB model. In addition, Madden *et al.* found the TPB to be a better predictor of behavior (R^2=0.38) when compared to the TRA (R^2=0.28) (Madden *et al.*, 1992).

Other studies investigating the utility of the TPB have found the model to be a relatively good predictor of behavioral intention and behavior. A 1998 meta-analysis conducted by Notani (1998) assessed the utility of the TPB, specifically examining the PBC construct. The investigator found the model to be a good predictor of behavioral intentions. In his analysis, Notani reviewed 63 studies using the TPB. The types of studies reviewed included those assessing behaviors such as exercise programs, breast self-exams, voting, gift giving, weight loss, alcohol consumption, and others. Results of the meta-analysis found significant correlations between intention and each of the constructs: the I-B relationship (R=0.38, $p<0.01$), the A_o-I relationship (R=0.37, $p<0.01$), the SN-I relationship (R=0.23, $p<0.01$), and the PBC-I relationship (R=0.16, $p<0.01$). However, results for the PBC-B relationship were somewhat weak (R=0.14, $p<0.10$). Overall, the TPB model performed well in the prediction of behavioral intentions and PBC served as a significant predictor of intention (Notani, 1998).

Armitage and Conner's (2001) meta-analytic review of the TPB found similar results. Their review of 185 studies that used TPB to assess various behaviors found that intention and PBC accounted for 27 percent of the variance in behavior and the A_o+SN+PBC constructs accounted for 39 percent of the variance in intention. The PBC-I correlation was considered to be strong (r=0.43) and accounted for 6 percent of the variance in behavior, when controlling for A_o+SN (Armitage& Conner, 2001).

Haggar *et al.* (2002) conducted a meta-analysis comparing the TPB model to the TRA model. Their analysis of 72 studies found the TPB model to be a much better predictor of behavioral intention when compared to the TRA. Results showed that the TPB model accounted for 45 percent of the variance in intention compared to the TRA which accounted for 37 percent (Hagger *et al.*, 2002).

The TPB has been found to perform well across a wide range of health-related domains (Montano& Kasprzyk, 2002). Godin and Kok (1996) reviewed the applications of the TPB in the domains of health behavior. The focus of their research was to verify the efficiency of the theory in predicting health behaviors. Researchers reviewed 56 studies examining patient behaviors which included addiction, driving, eating, health screening, eating, exercising, HIV/AIDS and oral hygiene. Fifty-eight behavioral and 87 intentional applications were examined for the above mentioned behaviors. Study findings indicated that attitude, subjective norms, and perceived behavioral control (A_o+SN+PBC) accounted for an average of 41 percent of the variance in intention. The investigators noted that variance in intention ranged according to the study categories (32% for eating disorders to 47% for hygiene behaviors). Each of the TPB's constructs were seen to be significant components in the prediction of intention. Attitude and perceived behavioral control were observed to account for most of the variance in intention among the studies examined. Further, when added to A_o+SN, the PBC accounted for an additional 13 percent of the explained variance in intention. Subjective norms appeared to explain less of the variance in intentions. The model's ability to predict behavior yielded an average R^2 of 0.34. The investigators concluded that the TPB performs well across various health-related behaviors. However, the efficiency of the theory varies among health-related behavior categories (Godin& Kok, 1996).

Like the TRA, most of the health-related TPB studies reviewed were focused on predicting the intentions and behavior of patients/consumers. Because of the nature of this project, the remainder of the review will be limited to TPB studies examining the behaviors of health providers administering care. The following two categories of TPB studies are briefly examined: (1) research studies examining physicians' intentions-behaviors and (2) studies assessing health care providers' intentions to use opioid analgesics to treat patients in pain.

Few studies were found that utilized the TPB to assess physician behavior (Table 3.6), but all concluded that the TPB was a relevant predictor of behavior among health care providers (Nash *et al.*, 1993; Godin& Kok, 1996; Millstein, 1996; Lambert *et al.*, 1997; Edwards *et al.*, 2001; Walker *et al.*, 2001; Limbert& Lamb, 2002)

Table 3.6 Review of Studies Using the Theory of Planned Behavior to Predict Intentions of Healthcare Provider Behaviors

Study	**Behavior**	**Sample (N)**	**Semipartial Correlation Coefficient(sr^2) / Beta Weights (β) for A_O-I**	**Semipartial Correlation Coefficient(sr^2) / Beta Weights (β) for SN-I**	**Semipartial Correlation Coefficient(sr^2) / Beta Weights (β) for PBC-I**	**Intention (I) I=A+SN+PBC Model R^2**
Physician Studies						
Millstein, 1996	Counseling adolescents on sexually transmitted diseases	765 primary care physicians	β=0.05	β=0.19***	β=0.36***	R^2=0.40***
Walker *et al.*, 2001	Prescribing antibiotics	126 general practitioners	β =0.33**	β=-0.08	β=0.36**	R^2=0.48***
Limbert and Lamb, 2002	Guideline adherence: 1)Asthma guidelines 2)Antibiotic guidelines	 223 junior physicians 214 senior surgeons	 β =0.15**** β =0.64****	 β=0.58**** β =0.11****	 β=0.17**** β =0.10****	 R^2=0.58**** R^2=0.52****
Nursing Studies						
Nash *et al.*,1993	Conducting pain assessments	100 registered nurses	β =0.10	β =-0.09	β =0.46***	R^2=0.21***
Edwards *et al.*, 2001	Administering Opioids	446 hospital nurses	sr^2=0.22**	sr^2=0.29**	sr^2=0.32**	R^2=0.39**

A_o-I = Attitudes-Intention, SN-I = Subjective Norms-Intention, PBC-I = Perceived Behavioral Control-Intention, na = not available
*p<0.05, **p<0.01, ***p<0.001, ****significant (p value not indicated)

TPB Physician Studies

The Millstein study examined the utility of the TPB and the TRA in assessing physicians' behavioral performance of preventative health service behaviors (Millstein, 1996). A prospective study of 765 physicians found the TPB to be a significant predictor of counseling behaviors among physicians. Multiple regression analysis indicated that the TPB constructs (A_o+SN+PBC) were significant predictors of intention, yielding an R^2 of 0.27 ($p<0.0001$). The model also yielded significant beta weights for attitudes ($\beta=0.11$, $p<0.0001$), subjective norms ($\beta=0.21$, $p<0.0001$), and perceived behavioral control ($\beta=0.37$, $p<0.0001$). The model's constructs accounted for 27 percent of the variance in intention. An additional regression analysis was conducted to determine whether the addition of PBC added to the predictability of behavioral intention. PBC was entered in as a separate, last step. Results showed the change in R^2 to be significant ($R^2=0.12$, $p<0.001$), indicating that PBC improved the predictability of the model. Analysis of actual physician behavior found significant effects for subjective norms ($\beta=0.19$, $p<0.0001$) and perceived behavioral control ($\beta=0.36$, $p<0.0001$), however attitude had a non-significant effect in predicting behavior ($\beta=0.06$, $p> 0.05$). The TPB model accounted for 40 percent of the variance in subsequent behavior. To assess whether PBC had a direct effect on behavior above and beyond its effects through intention, PBC was simultaneously regressed onto the three constructs (A_o+SN-I). The beta weight for PBC ($\beta=0.18$, $p<0.0001$) showed it to have a direct effect on behavior. Interpretation of the study results indicated that physicians who believed they had more control over the situation had greater intentions to provide preventative services. In all, Millstein found the TPB model to account for 27 percent of the variance in intention compared to the TRA which predicted 15 percent of variance. The TPB accounted for slightly more variance in behavior (40 percent) compared to the TRA (37 percent). Overall, the TPB model was observed to be a better predictor of intentions and behavior (Millstein, 1996).

TPB Prescribing Studies

Few studies have used Ajzen and Fishbein's models to understand physicians' prescribing behavior (Walker *et al*, 2001; Limbert and Lamb*,*2002). In a 2001 study, Walker and colleagues used the TPB to examine antibiotic prescribing intentions of primary care physicians (Walker *et al.*, 2001). In their cross-sectional study of 126 general practitioners, researchers investigated the strength of intention to prescribe antibiotics. Results of the study found the TPB predictor variables (A_o+SN+PBC) to explain 48 percent of the variance in intention to prescribe. The most important independent predictor variables was direct attitude ($\beta=0.33$, $p<0.01$). Indirect attitude and subjective norm were considered a non-significant predictor of physicians' willingness. However, control beliefs ($\beta=0.36$, $p<0.01$) were seen to be significant. Overall, the investigators concluded that the TPB model was statistically significant ($F=22.02$, $p<0.0001$) in predicting physicians' future prescribing intentions.

Limbert and Lamb (2002) conducted two TPB studies examining factors that influence physicians' use of guidelines (both studies were published in the same article). The first TPB study examined the intentions of 223 junior physicians to use guidelines for the management of acute asthma in the emergency room. Multiple regression analysis revealed subjective norm to be the strongest predictor of intentions (Attitude, $\beta=0.15$; SN, $\beta=0.58$; PBC, $\beta=0.17$; no p values given). Results showed that the TPB model explained 58 percent of the variance in physicians' intention scores. Subjective norm was found to share a considerable amount of variance with attitude ($r=0.48$, $p<0.001$). It is important to note that investigators modified the attitude variable to include three items (individuality, evidence, and useful) to assess physician behavior. Since they did not use "traditional" attitude questions for the asthma study measure, the construct may have been assessed incorrectly (Limbert& Lamb, 2002). Limbert and Lamb's second study examined the intentions of a more senior group of physicians. Investigators surveyed 214 surgeons to assess their intentions to follow antibiotic prescribing guidelines. Unlike the previous study, attitudinal item-measures used for this study adhered more closely to "traditional" TPB measures. Findings showed the model predicted 52 percent of physician intentions to adopt the clinical guidelines. Attitude was found to be a better predictor of intention in this particular study (Attitude, $\beta=0.64$; SN, $\beta=0.11$; PBC, $\beta=0.10$, no p values given). Investigators further analyzed this study using the "non-traditional" attitudinal measures (evidence, individuality, and useful). Results showed subjective norm as the strongest predictor for intention. Attitude and perceived behavioral control also accounted for a substantial amount of variance (Attitude, $\beta=0.25$; SN, $\beta=0.38$; PBC, $\beta=0.23$; no p values given). Investigators concluded that the results from each study model provided support for the use of the TPB to explain physician behavior. Findings from both studies appear to suggest that intentions among junior physicians to use guidelines are influenced to a greater extent by subjective norm and perceived behavioral control, while intentions of more senior physicians seem to be more greatly influenced by attitudes. This could be a function of physician experience (Limbert& Lamb, 2002). The authors pointed out that the differences between the two studies suggest that different factors are relevant to decision making with regards to the different guidelines (Limbert& Lamb, 2002).

TPB Pain Management Studies

The TPB has been used in studies to assess health providers' intentions and behaviors toward pain management. A Nash *et al.* (1993) study found nurses' intentions to conduct pain assessment was predicted by attitude, subjective norm, and perceived behavioral control. Their study of 100 Australian nurses found the TPB model to account for 21 percent of the variance in behavioral intention. Results showed attitude and subjective norm to be non-significant within the model (Attitude, $\beta=0.10$; SN, $\beta=-0.09$). However, perceived behavioral control made a large and significant contribution to the prediction of intention (PBC, $\beta=0.46$, $p<0.001$). Results for this study are questionable. Investigators pointed out several methodological issues regarding this research study. First, the small sample size limited the power of the study. More importantly, the nursing population who identified the relevant behavioral and normative beliefs was different from that of the main sample. These and other limitations may have affected results of the attitude and subjective norm constructs (which contributed relatively little to the model). However, investigators indicated that the perceived behavioral control findings were consistent with results found in previous TPB studies (Nash *et al.*, 1993).

During this literature search, only one published study was found using the TPB to examine health care providers' intentions to use opioids to treat patients' pain. Edwards *et al.* (2001) used the TPB to examine nurses' intentions to administer opioids for pain relief. In their cross-sectional study of 446 hospital nurses, researchers investigated the behavioral intention to administer opiate analgesics as needed (p.r.n.) to patients in pain. Multiple regression yielded a significant R of 0.63 ($F_{4,441}$=708, $p<0.01$). Direct attitude, indirect belief-based attitude, subjective norms, and direct control variables were observed as significant independent contributors to intention (Direct attitude, sr^2=0.22; Indirect attitude, sr^2=0.13; SN, sr^2=0.29; PBC, sr^2=0.32, $p<0.01$). Overall, 39 percent of the variability in nurses' intention was predicted by the model. Results showed nurses to have an overall positive attitude towards opioids and their use in pain management. Social norm appeared to play an important role in their decisions to administer opioids (i.e., nurses were influenced by patients, medical staff, and colleagues). Perceived control in opioid administration p.r.n. was strong among nurses. Edwards *et al.* concluded that their model supported the TPB's ability to predict nurses' intentions, however, they expressed a need to further explore the unexplained factors affecting the remaining 60 percent of variation in intention scores (Edwards *et al.*, 2001).

Limitations of TPB

Overall the TPB provides a well-defined framework to examine behaviors that are not under complete volitional control. The TPB has been shown to be a useful model in predicting intentions from attitude, subjective norm and perceived behavioral control. However, like the TRA, it does have several limitations that should be addressed (refer to Limitations of TRA Section 3.3.4). Some of these limitations include the following: (1) the model is applicable only to individuals who are considered "rational actors," (2) the model has reduced predictive ability for cross-sectional studies, (3) poorly conducted elicitation interviews may result in inadequate identification of salient belief items, and

(4) the model is designed specifically to predict behavioral intentions which is assumed to lead to actual behavior (Montano& Kasprzyk, 2002; Ajzen& Fishbein, 2004).

Studies have shown the TPB to significantly contribute to the prediction of health care professionals' (e.g., physicians, nurses) intentions to deliver health-related services to patients/consumers. The model has been useful in better understanding health providers prescribing and pain management behaviors. As a result, the TPB model may be useful for predicting physicians' intentions (willingness) to provide pain management services to patients/consumers. Additional studies should be conducted to further examine the decision-making process among physicians to better predict health-related intentions and behaviors.

3.5 Theoretical Framework

In order to examine family physicians' willingness to prescribe CR opioids to patients with moderate to severe CNMP, a theoretical model was designed to predict willingness. As previously discussed, the TRA and TPB are two models that have been used extensively to explain and predict health-related intentions and behaviors. Due to the nature of the proposed study, the TPB will be used as the social cognitive model. The models' ability to assess behaviors that may not be under the complete volitional control of the physician makes this an appropriate model for assessing physician intentions (and behaviors). The addition of the PBC construct to the attitude and subjective norm constructs may allow the model to better assess intention and behavior. Therefore, the TPB was used to predict family physicians' willingness to prescribe CR opioids to patients with moderate to severe CNMP.

The term "willingness" was used in place of "intention" for the study model. The concept of intention involves a level of planning and commitment to engage in a particular behavior. Similar to the intention construct, willingness can be used to assess behavior through the use of predictor variables found under Ajzen and Fishbein's theoretical model. However, unlike intention, the willingness component is described as concerning a relative lack of planning or premeditation (Gibbons& Gerrard, 1995;

Gibbons *et al.*, 1998). For example, willingness questions are interested in "what are you willing to do?" which is not the same as "what are you planning to do?" The primary distinction involves the reactive rather than deliberative nature of willingness. The willingness variable has been used in studies that involve assessing risk-like behaviors. Some of these studies include behaviors such as smoking, drinking, reckless driving and contraception (Gibbons& Gerrard, 1995). The willingness measure has been applied to assess behavioral intentions of health providers. For example, it has been used in a study examining clinical psychology students' willingness to interact with patients with HIV(Berger& O'Brien, 1998). More recently, it has been used to assess pharmacists' willingness to dispense syringes to known or suspected intravenous drug users (Mashburn, 2004). The controversies surrounding both the legitimate and illegitimate use of opioids may make willingness a more suitable measure than intention. Therefore, willingness may be a more appropriate measure for this study.

The recent past behavior variable was added to the model. Past experience with the behavior of interest is considered to provide important information in regards to future behavior (Ajzen,1991). Furthermore, prior behavior has been shown to add to the predictability of the TPB (Millstein, 1996; Walker *et al.*, 2001). In Walker *et al.'s* study, inclusion of the past prescribing behavior variable (β =0.58, $p<0.01$) to the TPB model significantly improved the proportion of the variance explained in physicians' intentions to prescribe antibiotics to 63 percent (R^2 change =0.15, F change=45.57, $p<0.0001$). Similar effects were seen in the Millstein (1996) study where by adding physicians' previous counseling behavior to the TPB increased the amount of variance predicted by the model to 42 percent (R^2 change=0.05, $p<0.001$).

A continuing medical education (CME) variable was also added to the model. Researchers have found that CME training in pain management improved physicians' knowledge and beliefs toward prescribing opioids for CNMP (Morley-Forster *et al.*, 2003). Further, similar studies have shown that physicians receiving up-to-date education on opioids in pain management could hold more positive beliefs toward using CR opioids when treating patients with chronic pain (Gilson& Joranson, 2001; Gourlay *et al.*, 2004; McCarberg, 2004; Potter *et al.*, 2004; Otis& Fudin, 2005). It is therefore important to examine the relationship between physician continuing education in pain management and the TPB model.

Geographic location was examined in this study. Practice location may provide important information in regards to physicians' attitudes, perceived behavioral control, and willingness toward CR opioids. Studies have found that physician respondents practicing in rural areas generally hold more negative views toward opioids compared to physicians in larger communities (Weinstein *et al.*, 2000). Further, compared to urban family physicians, rural family practitioners were less knowledgeable about pain management (Probst *et al.*, 2002). Therefore, it is important to examine the relationship between practice location and the TPB variables.

Figure 3.4 Study Model

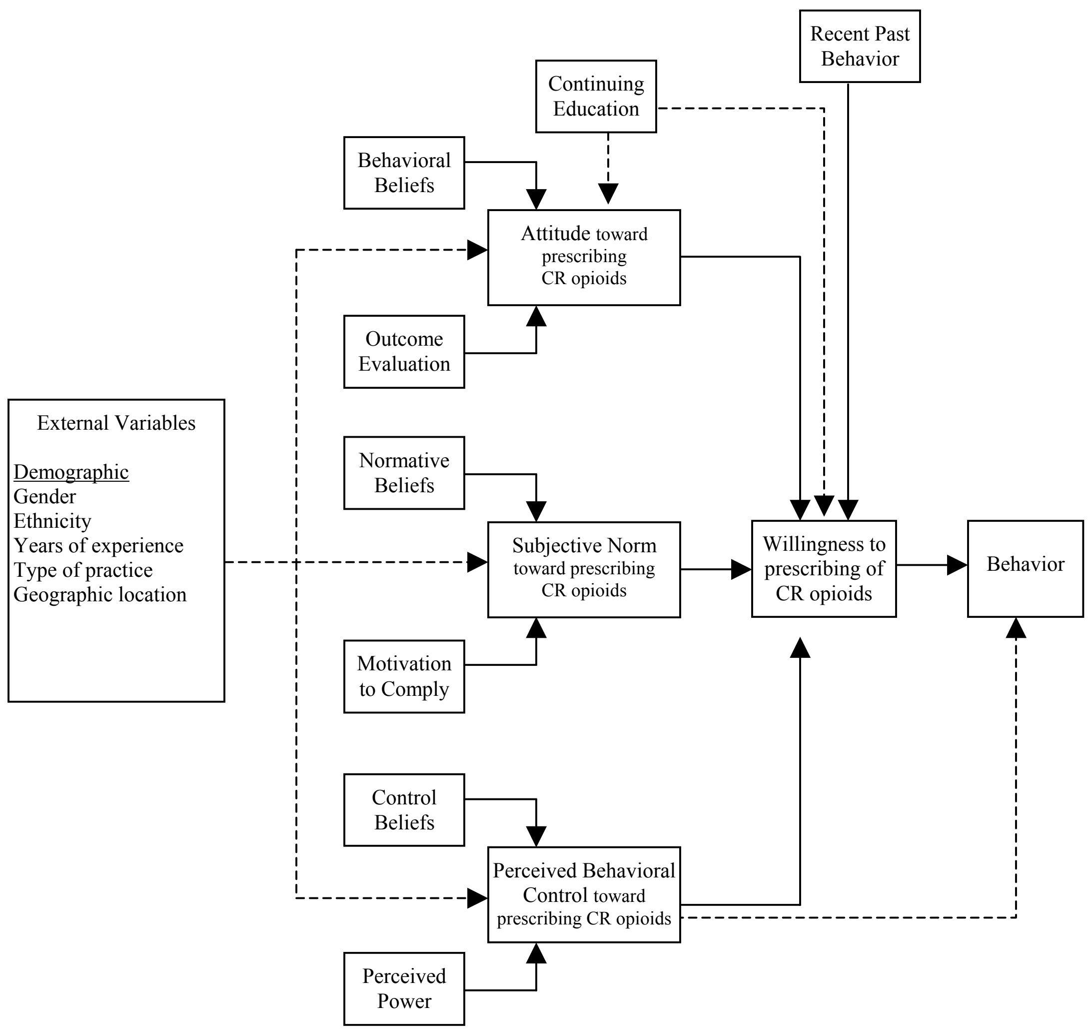


Figure 3.4 illustrates the model for the proposed study. According to the model, family physicians would be more willing to prescribe CR opioids to patients with moderate to severe CNMP if they held favorable attitudes toward the target behavior. Further, physicians should be willing to prescribe CR opioids to CNMP patients if favorable subjective norms are present, supporting the behavior of interest. Third, the model illustrates that physicians' willingness to prescribe will increase with higher levels of perceived behavioral control over prescribing CR opioids. Fourth, recent past

behavior (previous prescribing behavior) is also expected to directly affect willingness to prescribe CR opioids. Finally, continuing education is expected to have a positive relationship with attitudes and willingness.

3.6 Objectives and Hypotheses

The purpose of this study was to achieve a better understanding of why physicians are willing or not willing to prescribe controlled-release (CR) opioids to patients diagnosed with moderate to severe chronic non-malignant pain (CNMP). A social cognitive model, the Theory of Planned Behavior (TPB), was be used to achieve a better understanding of this health-related willingness formation.

A review of the literature has shown that individuals who hold favorable attitudes toward a specific behavior, who are strongly influenced by supportive social norms and who have high perceived behavioral control over the behavior are more likely to form intentions (i.e., be willing) to perform the target behavior. The following objectives and hypotheses (H_i) were examined using the TPB model. Objectives and hypotheses were discussed in more detail in Chapter 4, Methodology.

Objective 1: To explore the utility of the TPB constructs (attitude, subjective norm, perceived behavioral control) and the predictive strength of each TPB component in predicting family physicians' willingness to prescribe CR opioids to treat patients with moderate to severe CNMP.

H1: Attitude, subjective norm, and perceived behavioral control constructs will explain a significant amount of variance in physicians' willingness to prescribe CR opioids to patients with moderate to severe CNMP.

H2: Favorable attitudes will be a positive and significant predictor of willingness to prescribe CR opioids to patients with moderate to severe CNMP, while controlling for subjective norm and perceived behavioral control.

H3: Social norms supporting the prescribing of CR opioids to patients with moderate to severe CNMP will be a positive and significant predictor of willingness to prescribe, while controlling for attitudes and perceived behavioral control.

H4: Strong perceptions of behavioral control will be a positive and significant predictor of willingness to prescribe CR opioids to patients with moderate to severe CNMP, when controlling for attitude and subjective norm.

Objective 2: To determine if the perceived behavioral control construct adds to the prediction of family physicians' willingness to prescribe CR opioids to patients with moderate to severe CNMP beyond the attitude and subjective norm constructs.

H5: The perceived behavioral control construct will significantly increase the explanatory power of the regression model compared to only using attitude and subjective norm to explain family physicians' willingness to prescribe CR opioids to patients with moderate to severe CNMP.

Objective 3: To determine if the recent past behavior (RPB) construct adds to the prediction of family physicians' willingness to prescribe CR opioids to patients with moderate to severe CNMP (beyond the TPB constructs).

H6: The recent past behavior construct will significantly increase the explanatory power of the regression model compared to only using the TPB constructs to explain physicians' willingness to prescribe CR opioids to treat moderate to severe CNMP patients.

Objective 4: To determine if family physician willingness and attitude toward prescribing CR opioids to patients with moderate to severe CNMP differs by the level of exposure to continuing education (CE) in pain management.

H7: Physicians who have received CE in pain management will be more willing to prescribe CR opioids to moderate to severe CNMP patients versus physicians who have not received CE.

H8: Physicians who have received CE in pain management will have more favorable attitudes toward prescribing CR opioids to patients with moderate to severe CNMP versus physicians who have not received CE.

Objective 5: To determine if family physicians' attitude, subjective norm, or perceived behavioral control toward prescribing CR opioids to patients with moderate to severe CNMP differs by geography.

H9: Family physicians who practice in suburban areas will have a significantly more favorable attitude toward prescribing CR opioids to patients with moderate to severe CNMP versus family physicians who practice in rural or urban areas.

H10: Family physicians who practice in suburban areas will have significantly more favorable social norms supporting the prescribing CR opioids to patients with moderate to severe CNMP versus family physicians who practice in rural or urban areas.

H11: Family physicians who practice in suburban areas will have a significantly stronger perception of behavioral control in prescribing CR opioids to patients with moderate to severe CNMP versus family physicians who practice in rural or urban areas.

Objective 6: To determine if family physicians' attitude, subjective norm, or perceived behavioral control toward prescribing CR opioids to patients with moderate to severe CNMP differs by physician demographics and practice characteristics.

H12: There is no difference in physicians' attitudes toward prescribing CR opioids to moderate to severe CNMP patients between male and female physicians.

H13: There is no difference in physicians' subjective norm when prescribing CR opioids to moderate to severe CNMP patients between male and female physicians.

H14: There is no difference in physicians' perceived behavioral control over prescribing CR opioids to moderate to severe CNMP patients between male and female physicians, controlling for

H15: There is no difference in physicians' attitudes toward prescribing CR opioids to moderate to severe CNMP patients and years of experience.

H16: There is no difference in physicians' subjective norm when prescribing CR opioids to moderate to severe CNMP patients and years of experience.

H17: There is no difference in physicians' perceived behavioral control over prescribing CR opioids to moderate to severe CNMP patients and years of experience.

H18: There is no difference in physicians' attitudes toward prescribing CR opioids to moderate to severe CNMP patients and physician ethnicity.

H19: There is no difference in physicians' subjective norm when prescribing CR opioids to moderate to severe CNMP patients and physician ethnicity.

H20: There is no difference in physicians' perceived behavioral control over prescribing CR opioids to moderate to severe CNMP patients and physician ethnicity.

H21: There is no difference in physicians' attitudes toward prescribing CR opioids to moderate to severe CNMP patients and type of practice.

H22: There is no difference in physicians' subjective norm when prescribing CR opioids to moderate to severe CNMP patients and type of practice.

H23: There is no difference in physicians' perceived behavioral control over prescribing CR opioids to moderate to severe CNMP patients and type of practice.

3.7 Summary

In summary, the TPB has been established in the literature as a useful predictor of behavioral intentions. The theory is a well-developed and tested behavioral model that has been successfully used to predict a variety of health-related behaviors. The attitude, subjective norm, and perceived behavioral control constructs are useful in predicting behaviors not under complete volitional control. More recently, studies have demonstrated that the TPB model is not only useful in predicting behaviors among patients/consumers but also among health care providers. Furthermore, the model has been shown to predict the treatment intentions of nurses and physicians. The TPB model may be useful for predicting physicians' willingness to provide pain management services, particularly in the use of controlled substances for the treatment of persistent non-life threatening pain. This research project recognizes the utility of the TPB in predicting the health-related intentions and behaviors of health care providers. Therefore, the model was used to further examine the decision-making process of physicians regarding their willingness to prescribe CR opioids to patients with CNMP.

CHAPTER 4: METHODOLOGY

This study was designed to examine family physicians' (FPs) willingness to prescribe controlled-release opioids (CR opioids) to patients experiencing moderate to severe chronic non-malignant pain (CNMP). As mentioned in Chapter 3, the Theory of Planned Behavior (TPB) was used to examine the predictors (attitude, subjective norm, and perceived behavioral control) of willingness to prescribe. Recent past behavior (RPB), continuing education (CE), and physician demographic/practice characteristic variables were also examined. This chapter outlines the research methodology that was used to conduct the study. The chapter is divided into five major sections: (1) Study Design, (2) Instrument Development, (3) Instrument Distribution, (4) Data Collection, and (5) Data Analyses.

4.1 Study Design

A *cross-sectional non-experimental survey design* was employed for this study. Based on the exploratory nature of this research, the study design falls under the "ex post facto" or correlational research design (Polit& Hungler, 1995). The study used a self-report web-survey data collection instrument (i.e., electronic questionnaire) to measure factors that may influence physicians' willingness to prescribe CR opioids for patients with CNMP. The electronic questionnaire instrument was used to capture physician responses.

4.1.1 Group Selection

The study population selected for this research study were FPs actively practicing in Texas. FPs were chosen because of their level of exposure in treating diverse patient populations seeking medical care for CNMP (refer back to Chapter 2, Section 2.6).

The population utilized in this study included all members of the Texas Academy of Family Physicians (TAFP) actively practicing in Texas (2006 calendar year). TAFP members were chosen based on the following reasons: (1) the TAFP membership represents approximately 5,354 of the 7,009 registered family physicians practicing in the state of Texas (Texas Medical Board, 2006); (2) researchers had access to FP focus groups through the TAFP organization; (3) researchers had access to the study population's e-mail listing to send electronic questionnaires; and (4) budget constraints required a cost-efficient mode of administering surveys to the target group.

4.1.2 Inclusion and Exclusion Criteria

Inclusion Criteria

Participants eligible for this study were "active TAFP members." The study population was comprised of male and female FPs of various backgrounds and experience levels. It was assumed that FP participants were knowledgeable in the uses of CR opioids to treat pain, had attained prescribing privileges through the Texas Department of Public Safety and had a controlled substances license granted to them by the Drug Enforcement Agency. The 2006 TAFP membership database served as the study population data source.

The inclusion criteria for this study were as follows:

1. Active member of the TAFP currently practicing in the state of Texas;
2. Texas medical board (TMB) certified family physician (or licensed physician actively seeking board certification);
3. Valid e-mail address listed in the TAFP membership database;
4. Physician with access to a computer that has the required web-browser software to complete the electronic questionnaire; and
5. Access to the Internet.

Exclusion Criteria

As stated previously, the purpose of this study was to measure predictors of family physicians' willingness (intention) to prescribe CR opioids to patients with CNMP. Since physicians who were not actively practicing were unlikely to be exposed to current pain management barriers (discussed in chapters 1, 2, and 3), they were ineligible to participate in this study. Additionally, TAFP members not licensed by the TMB or not actively seeking licensure were excluded from the study. Exclusion of these individuals enhances the generalizabilty of study findings to only family physicians practicing in Texas.

4.1.3 Target Population

The target population for this study was all actively practicing Texas family physicians. The accessible population for this study was TAFP members with e-mail addresses in the TAFP database. Researchers had access to the entire TAFP membership e-mail listing. As a result, the sampling frame for this study included all TAFP members who conformed to the designated inclusion criteria.

4.1.4 IRB Procedures

This research study followed survey procedures as outlined by The University of Texas Institutional Review Board (IRB). The project was approved by the University of Texas at Austin's IRB.

4.2 Instrument Development

The survey instrument was developed to measure the following Theory of Planned Behavior constructs: attitude (A_o), subjective norm (SN), and perceived behavioral control (PBC). Recent past behavior (RPB), continuing education (CE) and physician demographics/ practice characteristics were also assessed. The instrument was developed from information gathered from the literature and through elicitation interviews (focus groups). A pretest of the instrument was conducted among a representative sample of 15 family physicians (refer to Section 4.3).

4.2.1 Focus Groups

The purpose of conducting the focus group (i.e., elicitation) interviews was to identify relevant behavioral belief items, referents perceived to influence physician's willingness , and control beliefs. Following the recommendations of Fishbein and Ajzen (1980), three focus group interviews were conducted in 2005 among a total of 15 family physicians. Participants were asked to respond to three general categories of questions, as they related to the TPB. First, participants were asked to describe the perceived advantages and disadvantages of prescribing CR opioids to patients with CNMP. Second, participants were asked to identify and describe any important individuals or groups (referents) that may influence their prescribing behavior. For example, participants were asked to list referents that are either in favor or opposed to physicians prescribing CR opioids to patients with CNMP. Third, physicians described their control beliefs over prescribing CR opioids. Identified salient beliefs and related data gathered from the three focus groups were used to develop the questionnaire items for the pretest.

Physician Focus Group Procedure

The TAFP membership coordinator was contacted to assist in planning and implementing a recruitment strategy of volunteer family physician participants. A list of names and e-mail addresses were obtained of TAFP members actively serving on a TAFP committee who may be willing to participate in the focus groups. An e-mail invitation was sent to TAFP committee members to participate in focus groups conducted during either of the two TAFP conferences held in 2005. Researchers attempted to recruit 10 volunteers for each interview session via e-mail in an effort to meet the minimum recommended focus group size. Focus group volunteers were contacted twice via e-mail to remind them of the time, date and location of their respective focus group meetings. The first contact was one week before the scheduled focus group meeting date and the second contact was two days before the meeting.

Prior to conducting the focus groups, an interview guide was developed to help focus and guide the discussions (Appendix A). Focus group questions were created from criteria developed by Ajzen and Fishbien (Ajzen& Fishbein, 1980; Ajzen, 1991).

Three focus groups were conducted to collect data on behavioral, normative, and control beliefs, held among TAFP physicians about the use of CR opioids for moderate to severe CNMP. Responses were gathered in the form of open-ended elicitation interviews. The first focus group took place in Austin, Texas. This focus group was comprised of three family physician volunteers who were attending a TAFP conference. The second focus group took place on day two of the conference and was comprised of six family physicians. The third focus group was also comprised of six family physician volunteers who were attending a different TAFP conference in San Antonio, Texas.

For this research study, each focus group lasted one to two hours and asked physicians to elicit responses on the following salient belief item questions:

Behavioral beliefs

1. Identify the perceived advantages associated with family physicians prescribing CR opioids to treat patients with moderate to severe CNMP.

2. Identify the perceived disadvantages associated with family physicians prescribing CR opioids to treat patients with moderate to severe CNMP.

3. Identify other perceived advantages or disadvantages associated with family physicians prescribing CR opioids to treat patients with moderate to severe CNMP.

Normative beliefs (referents)

4. Identify individuals or groups who would approve of family physicians prescribing CR opioids to treat patients with moderate to severe CNMP.

5. Identify individuals or groups who would not approve of family physicians prescribing CR opioids to treat patients with moderate to severe CNMP.

6. Identify other individuals or groups who would or would not approve of family physicians prescribing CR opioids to treat patients with moderate to severe CNMP.

Control beliefs

7. Identify perceived factors that would make it easier for family physicians to prescribe CR opioids to treat patients with moderate to severe CNMP.

8. Identify perceived factors that would make it difficult for family physicians to prescribe CR opioids to treat patients with moderate to severe CNMP.

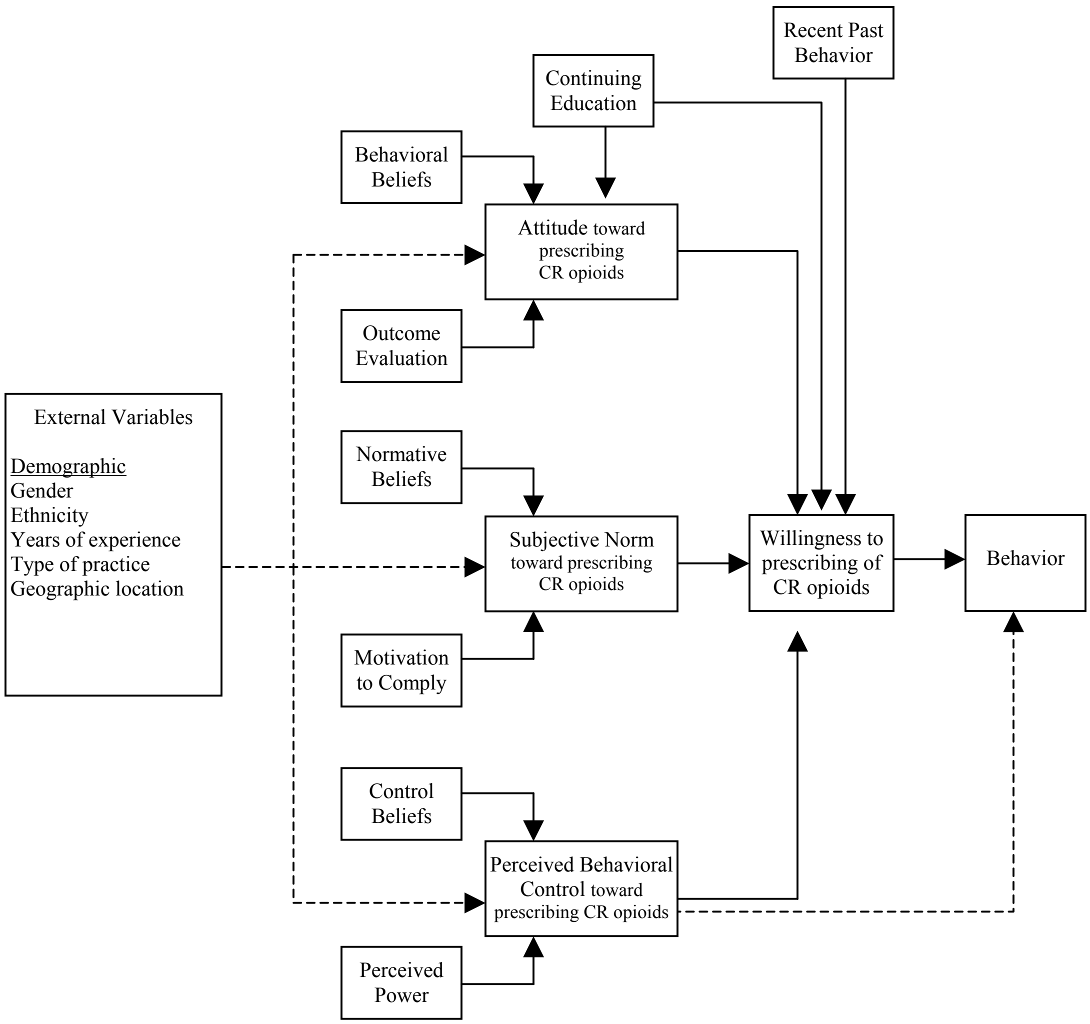
9. Identify other perceived factors that would make it easier or more difficult for family physicians to prescribe CR opioids to treat patients with moderate to severe CNMP.

As recommend by Ajzen and Fishbein (1980), a minimum of five to nine of the most frequently mentioned outcomes (salient beliefs) discussed during the elicitation interviews were used to construct the survey instrument. The results section will discuss modal beliefs elicited during the focus group sessions and describe techniques used in selecting salient beliefs for each of the constructs.

4.2.2 Study Variables

This section describes the independent and dependent variables that were used for this study. The following TPB constructs were examined: (1) Attitudes, (2) Subjective Norms, (3) Perceived Behavioral Control, and (4) Behavioral Intention (i.e.,Willingness). Information about the Recent Past Behavior, continuing education, and other demographic variables were also be collected and examined. Figure 4.1 is the conceptual model for this study.

Figure 4.1 The Conceptual Model: Using TPB to Predict Physicians' Willingness to Prescribe CR opioids to Treat Patients with Moderate to Severe CNMP



Independent Variables

According to Fishbein and Ajzen (1980), the most important determinant of behavior is behavioral intention (willingness). As seen in Figure 4.1, under the TPB model, the direct determinants of the physician's willingness to prescribe CR opioids are his/her attitude toward the behavior, the subjective norm associated with the behavior, and the perceived behavioral control over the behavior of interest. Recent past behavior was also included in the model as a direct predictor of willingness. The details of each predictor variable are described below.

Attitude

Attitude *(*A_o*)*, as defined by Fishbein and Ajzen (1975) is "a learned predisposition to respond in a consistently favorable or unfavorable manner with respect to a given object." As previously discussed in Chapter 3, attitude can be determined through the assessment of a person's beliefs about performing the behavior of interest, weighted by an evaluation of the outcomes or attributes of performing the behavior of interest. Attitude can either be a positive or negative evaluation toward performing a behavior.

For this study, A_o was operationalized as the beliefs and perceived likelihood of outcomes relative to the use of CR opioids to treat patients with moderate to severe CNMP. A_o was assessed through direct and indirect measurement scales. The direct measure of attitude was assessed using a single multi-item question asking respondents their overall evaluation of the behavior of interest. This direct measure utilized a semantic differential scale (e.g., good–bad). Indirect measures of attitude were assessed by measuring the two variables of the A_o construct: behavioral beliefs (***b***) and outcome evaluation (***e***). For this study, ***b*** measured physicians' salient beliefs about prescribing CR opioids to patients with moderate to severe CNMP and ***e*** measured the evaluation of outcomes associated with the behavior. Indirect measures were assessed using two sets of questions, each using a bipolar scale (e.g., unlikely–likely; good–bad). The utilization of each of the measurement scales was important to this study, for two reasons. First, under the TPB framework, direct measures are more strongly associated with intention and behavior than are indirect measures (Montano& Kasprzyk, 2002). As a result, it was important to demonstrate the association between direct attitudes and intention before conducting analyses on indirect measures. Second, it was necessary to demonstrate that indirect measures are strongly associated with direct measures, in order to show confidence that the appropriate physician beliefs are being measured (refer to Chapter 3, Section 3.3.1).

As previously mentioned in the Focus Group Section 4.2.1, the independent variables used for each of these constructs were determined from data collected from the three focus group interviews conducted. Physicians' behavioral beliefs, ***b***, and outcome evaluations, ***e***, were determined from the responses gathered during focus group interviews. Once the ***b*** and ***e*** were identified, variable items were incorporated into the questionnaire to measure indirect physician attitudes.

As recommended by Ajzen (2002), both *direct* and *indirect* measurement scales were used in the questionnaire to assess physician attitudes. The questionnaire contains a multi-item *direct measure* attitude question. Direct attitude was measured using a 7-point bipolar semantic differential scale containing evaluative terms (adjectives) such as: extremely bad (-3)/ extremely good (+3) (Osgood *et al.*, 1957). Direct attitude questions were asked in the following manner:

Q: "I feel that prescribing long-acting opiates to patients with moderate to severe CNMP is…" [5 adjective items] *(Survey Q4)*

Indirect (belief-based) measure items were developed from information gathered from focus group interviews. An "attitude toward CR opioids scale" was constructed using the most salient behavioral belief items reported among focus group participants. The scale was designed to evaluate each of the identified beliefs. Each ***b*** was rated using a bipolar 7-point semantic differential scale ranging from extremely unlikely (-3) to extremely likely (+3). Behavioral belief questions were asked in the following manner:

Q: "How likely do you think the following outcomes will occur if you prescribe long-acting opiates to patients with moderate to severe CNMP?" [10 behavioral belief items] *(Survey Q2)*

Similar to assessing behavioral beliefs, the ***e*** scale was designed to measure each of the evaluative outcomes and attributes associated with the respective behavioral belief. Each ***e*** was rated using a bipolar 7-point semantic differential scale, ranging from extremely bad (-3) to extremely good (+3). Evaluative outcome questions were asked in the following manner:

> **Q:** "Even though you may not agree with the outcomes listed, how good or bad do you feel each of the following outcomes would be if you prescribed long-acting opiates to treat patients with moderate to severe CNMP?" [10 outcome evaluation items] *(Survey Q3)*

Calculating attitude belief items

As discussed in Chapter 3, attitudes toward prescribing CR opioids to treat CNMP patients were determined by multiplying the respondents' belief-strength toward using CR opioids by the evaluative outcomes (***b*** x ***e***) and then summed for the total set of belief items (Equation 1).

Equation 1. Attitude Formation
(based on expectancy-value model)

$$A_o = \Sigma\, b_i e_i$$

A_o = attitude toward object, issue, etc.
b_i = behavioral belief about object's attributes or about the act's consequences
e_i = evaluations of attributes or consequences

Source: (Ajzen and Fishbein, 1975)

For example, if a physician believes that it is somewhat unlikely (-2) that his/her prescribing CR opioids for CNMP leads to patient addiction and believes addiction would be extremely undesirable (-3), then the cross-product for the belief for that respondent is +6. (possible range -9 to +9) Hence, the physician's view that it is unlikely that prescribing CR opioids leads to addiction among his/her CNMP patients would positively influence his/her attitude score (i.e., contribute to an unfavorable attitude toward prescribing CR opioids for CNMP). Refer to Chapter 3, section 3.3.1 for a review of calculating the attitude construct.

Subjective Norm

Subjective norm (SN), as defined by Ajzen and Fishbein, is "a person's belief that most of his or her important others think he/she should or should not perform the behavior in question" (1980). The SN construct is based on an individual's expectations that important referents (i.e., groups or individuals) endorse his/her performing a specific behavior and evaluates the level of an individual's motivation to comply with each of the referents (Ajzen, 1991). For this study, SN was operationalized as the influence "others" may have on physicians' willingness to prescribe CR opioids to treat patients with moderate to severe CNMP.

Similar to attitudes, SN was assessed through *direct* and *indirect* measurement scales. The items used for the SN construct were developed from responses collected during the three focus group interviews. The survey instrument contained a single-item *direct measure* question to assess subjective norm. The direct measure SN question was measured using Osgood's bipolar 7-point semantic differential scale ranging from strongly disagree (-3) to strongly agree (+3) and asked the following:

Q: "If I prescribe long-acting opioids to treat patients with moderate to severe CNMP, most people who are important to me would approve?" [1 item] *(Survey Q7)*

Indirect (belief-based) measures of SN were assessed by measuring two variables: normative beliefs (***n***) and an individual's motivation to comply (***m***) with each of the referents of interest. Normative belief is an individual's belief of what other referents think he/she should do in a particular circumstance. Salient referents were determined by data gathered from focus group interviews.

Normative beliefs were measured using a bipolar 7-point semantic differential scale which ranged from extremely unlikely (-3) to extremely likely (+3). Normative belief questions were asked in the following manner:

> **Q:** "How likely is that each of the following individuals or groups would think that you should prescribe long-acting opioids to treat patients with moderate to severe CNMP?" [7 normative belief items] *(Survey Q5)*

Motivation to comply (***m***) is an individual's belief that he/she will do what referent groups or individuals think he/she should do. Similar to procedures used to assess normative beliefs, motivation to comply was measured by asking a series of question-items to determine how likely the individual would comply with the wishes of others. Motivation to comply was measured using a bipolar 7-point semantic differential scale ranging from extremely unlikely (-3) to extremely likely (+3). Motivation to comply questions were asked in the following manner:

> **Q:** "Generally speaking, how likely are you to do what the following individuals or groups want you to do when it comes to prescribing long-acting opioids to treat patients with moderate to severe CNMP?" [7 motivation to comply items] *(Survey Q6)*

Calculating normative belief items

Subjective norms were determined by multiplying the products of the respondents' normative beliefs by the corresponding motivation to comply (***n*** x ***m***) and then summing the products (Equation 2).

Equation 2. Subjective Norm Formation
(based on expectancy-value model)

$$SN = \Sigma\, n_i m_i$$

SN = Subjective norm toward the object
n_i = normative beliefs (strength)
m_i = motivation to comply (w/ the referent)

Source: (Fishbein& Ajzen, 1975)

For example, if a physician respondent indicated that his/her colleagues would be extremely likely (+3) to think that they should prescribe CR opioids to patients with moderate to severe CNMP and the respondent is extremely likely (+3) to comply with his/her colleagues wishes, then the cross-product for the SN for that respondent is +9 (possible range -9 to +9). Hence, the cross-product would indicate that the respondent's colleagues positively influence the physician's SN score (i.e., are supportive of him/her prescribing CR opioids for CNMP). Refer to Chapter 3, Section 3.3.2 for a detailed overview on calculating the SN construct.

Perceived Behavioral Control

The third construct that was assessed is perceived behavioral control (PBC). As defined by Ajzen, PBC refers "to an individual's perception of the ease or difficulty of performing the behavior of interest" (Ajzen, 1991).

For this study, PBC was operationalized as the perceived ease or difficulty for physicians to prescribe CR opioids to patients with moderate to severe CNMP.

Similar to attitude and subjective norm, the *direct* and *indirect measure* item-scales were utilized. The *direct measure* question-items asked physician respondents to rate their overall perceived control over prescribing CR opioids to treat moderate to severe CNMP patients. The survey instrument contained two single-item direct measure questions to assess PBC. The PBC questions were measured using a bipolar 7-point semantic differential scale ranging from strongly disagree (-3) to strongly agree (+3) and asked the following:

> **Q:** "It is easy for me to prescribe CR opioids to treat patients with moderate to severe CNMP." [1-item] *(Survey Q10)*

> **Q:** "I have complete control over whether or not I will prescribe CR opioids to treat patients with moderate to severe CNMP." [1-item] *(Survey Q11)*

Indirect (belief-based) measures of PBC were assessed by measuring the variables: control beliefs (***c***) and perceived power (***p***). To determine ***c*** and ***p*** items, focus group participants were asked to identify and describe factors (i.e., situations) that would make it easier or more difficult for them to prescribe CR opioids to CNMP patients. Responses collected were used to develop control belief and perceived power statements in the survey instrument.

Control beliefs (***c***) were measured using an indirect measurement scale. To determine *c*, respondents were asked to assess how much a specific factor would increase or decrease the difficulty of him/her performing the behavior of interest (i.e., prescribing CR opioids to patients with moderate to severe CNMP). Control belief questions were measured using a bipolar 7-point semantic differential scale ranging from extremely difficult (-3) to extremely easy (+3). Control beliefs were measured by asking the following question items:

> **Q:** "Will the following factors make it easier or more difficult for me to prescribe CR opioids to treat patients with moderate to severe CNMP?" [10 control-belief items] *(Survey Q8)*

Perceived power (***p***) was measured utilizing an indirect scale question. To determine ***p***, respondents were asked to respond to a multi-item question using a unipolar 7-point scale ranging from no control (+1) to complete control (+7). Perceived power questions determined how much control the respondents believed they had in a particular circumstance as it relates to the behavior of interest. Perceived power was measured by asking the following question:

> **Q:** "How much control do you feel you have over the following when it comes to prescribing CR opioids to patients with moderate to severe CNMP?" [10 perceived power items] *(Survey Q9)*

Calculating control beliefs

The indirect measures of PBC were determined by multiplying the cross-products of the respondent's control beliefs and perceived power (***c*** x ***p***). The cross-products were summed to give an index PBC score (Equation 3).

Equation 3. Perceived Behavioral Control
(based on expectancy-value model)

$$PBC = \Sigma\, c_i p_i$$

PBC = Perceived behavioral control
c_i = Control beliefs toward the factor under consideration
p_i = Perceived power of the control factor under consideration

Source: (Ajzen, 1991)

For example, having "access to pain management tools" was identified as one factor believed to affect a physician's perceived control over prescribing CR opioids to patients with CNMP. If a physician respondent believes (***c***) that having access pain management tools will make it somewhat easier (+2) to prescribe CR opioids to CNMP patients and he/she believes that they will have some control (***p***) in accessing pain tools (+4), then the mathematical cross-product for PBC is +8 (possible range -21 to +21). The score of the respondent indicates that, when considering access pain management tools, he/she feels they have a moderate level of positive control over prescribing CR opioids to CNMP patients,

Recent Past Behavior

One factor that was not originally included in the TPB model is recent past behavior (RPB). Studies have shown past behavior to be the best predictor of future behavior (Ajzen, 2002; Rhodes& Courneya, 2003). This study included the variable for RPB construct into the TPB framework. Two questions were used to measure recent past behavior. The first RPB question assessed physicians previous prescribing behavior using a 7-point scale ranging from never (+1) to always (+7). The following question was used to measure RPB:

Q: "How often did you prescribe long-acting opioids to patients with moderate to severe CNMP in the last month?" [1-item] *(Survey Q12)*

The second RPB question assessed previous prescribing behavior using a 5-point Likert scale ranging from never (+1) to always (+5). The following question was used to measure RPB by assessing the percentage of CNMP patients receiving CR opioids. This measure of RPB question was assessed by the following question:

Q: "How often do you prescribe long-acting opioids to patients with moderate to severe CNMP in the last month?"[1-item] *(Survey Q20)*

Continuing Medical Education

Respondents were asked five questions regarding their continuing medical education (CME) in pain management. The first question assessed if respondents received CME in pain management in the last three years dichotomous (yes/no). The second question asked respondents if they believed they had access to CME courses in pain management (using a bipolar 7-point scale ranging from strongly disagree (-3) to strongly easy (+3)). The third question inquired if they plan to attend any CME programs in pain management (using a bipolar 7-point scale ranging from very unlikely (-3) to very likely (+3)). The fourth question asked the likelihood of the respondent to attend a CME activity sponsored by TAFP (bipolar 7-point scale ranging from very unlikely (-3) to very likely (+3)). The fifth question asked the type of venue the respondent would prefer to receive CME in pain management (e.g., live, monograph, internet).

Demographic/Practice Characteristics

The following demographic and physician practice variables were collected (for actual questions refer to survey instrument in Appendix D):

- Gender;
- Ethnic background (African American/Black, Asian or Pacific Islander, Latino/Latin American/Hispanic, Native American/ Indigenous Peoples, White/European American, and Other);
- Physician practice experience (number of years respondent has been a practicing physician);
- Board certification (yes/no);
- Practice type (solo practice, partnership practice, physician group, managed care, hospital or clinical institution, or other);
- Practice location (urban, suburban or rural); and
- Average number of patients seen with CNMP per month.

Dependent Variable

Willingness

The dependent variable for this study was willingness (behavioral intention) to prescribe CR opioids to patients with moderate to severe CNMP. As discussed in Chapter 3, under the TPB structure, behavioral intention (BI) is based on the weighted sums of the predictors (A_o+SN+PBC) toward the behavior itself (Equation 4). Each predictor is weighted for its importance in relation to the specific behavior and population of interest (Ajzen, 1991).

Equation 4. Behavioral Intention

$$BI = (W_1)(A_o) + (W_2)(SN) +(W_3)(PBC)$$

BI = Behavioral Intention (Willingness)
$W_{1\text{-}3}$ = beta weight
A_o = Attitude
SN = Subjective Norm
PBC = Perceived Behavioral Control

Source: (Fishbein& Ajzen, 1975)

BI is seen to include a premeditated or a pre-planned response to the behavior of interest. However, the question of whether or not a physician's decision to use CR opioids when confronted with patients with CNMP is considered premeditated can be raised. Are physician prescribing behaviors premeditated or is it more spontaneous, based on the specific circumstance of the individual patient?

A search of the literature found several studies that examined this issue. Gibbons *et al.*(1998) proposed the prototype/willingness (P/W) model which adds elements of spontaneous reaction (reactiveness) to the behavioral theory. Still operating under the TPB framework, their model replaces the traditional concept of behavioral intention with the concept of willingness as a pre-determinant of actual behavior. The use of the P/W model has been supported by several studies (Berger& O'Brien, 1998; Gibbons *et al.*, 1998; Brown& Topcu, 2003; Mashburn, 2004; Pinsky *et al.*, 2004).

For this study, the willingness concept was used in place of the traditional behavioral intention construct. It was assumed that the actual behavior of prescribing CR opioids is preceded by a physician's willingness to use this type of opiate analgesic to treat moderate to severe CNMP patients (refer to Chapter 3, Section 3.3.3). Willingness for this study was operationalized as follows:

$$W = (w_1)(A_o) + (w_2)(SN) + (w_3)(PBC)$$

Willingness was measured using a bipolar 7-point differential scale ranging from extremely unlikely (-3) to extremely likely (+3). The following one-item question was used to measure willingness.

Q. "I am willing to prescribe CR opioids to treat patients with moderate to severe CNMP." [1-item] *(Survey Q1)*

The weighted sums of attitude, subjective norm, perceived behavioral control and recent past behavior was the framework for the willingness value. Beta weights for the predicted willingness formula were calculated using multiple regression analysis.

4.3 Pretesting Survey Instrument

The survey instrument was pretested to identify issues that may have affected survey length, face validity, content, clarity, format, and organization. The purpose of pretesting a survey was to identify any parts of the survey instrument that may be difficult for the target population of participants to read or understand and also to identify any parts of the data collection method that participants may find objectionable or offensive. The pretest also enabled researchers to determine whether the sequence of communications (e.g., e-mail cover letter, consent form, questions) are smooth and effective to determine the needs for training of researchers or data collection personnel, and to determine if measures yield data with sufficient variability.

A sample of 10 family physicians was invited to participate in a pilot study. Respondents participating in the pilot study were asked to provide feedback on the electronic questionnaire. Pretest study participants were then instructed to record the time it took them to complete the survey instrument, point out concerns regarding clarity and relevance of items, and indicate any issues on the format of the questionnaire. Respondents were asked to e-mail their written comments to the researchers. Instrument reliability was tested using Cronbach's alpha. The final survey instrument was submitted to the IRB for review and approval after it had been fully developed. TAFP members who participated in a focus group or pilot survey were excluded from the final survey sample.

4.4 Data Collection

This section describes the procedure that was employed to distribute the web-survey and collect survey responses.

Recognizing that surveys conducted among physicians can be different from surveying the general population, a review of the literature was conducted to determine appropriate methods for conducting web-surveys among physicians (Couper, 2000; Dillman, 2000; Dillman& Bowker, 2001; Kellerman& Herold, 2001; Couper *et al.*, 2004; Leece *et al.*, 2004; Olmsted *et al.*, 2005).

Historically, survey response rates have varied widely among health care practitioners (means ranging from 11% to 77%) (Raziano *et al.*, 2001; Braithwaite *et al.*, 2003; McMahon *et al.*, 2003; Leece *et al.*, 2004). A review of the literature found that a multiple contact technique involving pre-notification, and follow-up notification correspondence increased response rates among physicians and related health care professionals, compared to making a single contact (Raziano *et al.*, 2001; Braithwaite *et al.*, 2003; McMahon *et al.*, 2003). Further, the ability to minimize survey length and the use of progress indicators were associated with improved survey participation rates (Couper, 2000; Kellerman& Herold, 2001; Couper *et al.*, 2004; Leece *et al.*, 2004; Olmsted *et al.*, 2005).

This survey study employed Dillman's (2000) multiple notification technique to increase the likelihood of physician responses. The survey technique included the use of a pre-notification e-mail, an e-mail cover letter, and a follow-up e-mail reminder to increase awareness among the target population. In addition, attempts were made to shorten survey length to improve the response rate. Each of the methods has been shown to have a positive impact on the level of survey participation among respondents within the general population (McMahon *et al.*, 2003; Couper *et al.*, 2004; Olmsted *et al.*, 2005)

Pre-notification E-mail

For this study, a pre-notification e-mail was sent to eligible participants two weeks prior to the distribution of the "survey cover letter." The content of the pre-notification e-mail identified the study investigators, outlined the objectives of the study, included a link to the background of the study, and requested participation in the study. The e-mail also provided information on how participants may elect to be excluded from the survey and be excluded from receiving future e-mails from the investigators. A printed copy of the pre-notification e-mail is located in Appendix B.

Survey cover letter

Physicians were sent a survey cover letter e-mail two weeks after the pre-notification e-mail. This e-mail contained a hyperlink to the electronic questionnaire. The e-mail cover letter was sent to those study participants who did not "opt-out" of the study (this option was provided in the pre-notification e-mail). Similar to the pre-notification e-mail, the survey cover letter e-mail identified the research investigators, stated the study objectives, and contained a link directing study participants to the online consent form for the electronic questionnaire. A printed copy of the survey cover letter e-mail can be found in Appendix B.

Online consent form

Survey participants were directed to an online electronic "minimal risk" consent form. The online consent form resided on the TAFP computer web-server (at the tafp.org website). The consent form identified the title of the study, cited the IRB protocol number, identified the investigators of the study, described the purpose of the study, explained the activities participants were expected to complete as part of the survey process, identified the risks and benefits of the study, and included the confidentiality agreement. Study participants who consented to participate in the survey clicked on a form button labeled "I Agree" to proceed on to the electronic questionnaire. A printed copy of the online consent form can be found in Appendix C.

Electronic Questionnaire

Participants were automatically redirected to the electronic questionnaire once they had read the online consent form and consented to participate in the study by clicking the "I Agree" button. As this was an anonymous electronic questionnaire, no personally identifiable information was requested or collected from respondents. The electronic questionnaire resided on the TAFP's computer web-server. Questionnaire responses submitted by study participants were sent to an online Microsoft Access database residing on the TAFP's computer web-server. In order to protect the anonymity of the participant, response fields constructed to collect electronic responses were devoid of any unique identifiers. A printed copy of the electronic questionnaire can be found in Appendix D.

Follow-up E-mail.

Eligible participants were sent a follow-up e-mail two weeks after the survey cover letter e-mail. Due to the anonymity of the study, the e-mail was sent to all eligible study participants who did not opt-out of the study (from the pre-notification e-mail). The follow-up e-mail asked eligible participants to complete the electronic questionnaire, if they have not already done so. Similar to the survey cover letter e-mail, the follow-up e-mail identified the research investigators, restated the study objectives, and contained a link directing study participants to the online consent form for the electronic questionnaire. A printed copy of the follow-up cover letter e-mail can be found in Appendix B.

4.5 Data Analyses

Data used in the analyses came from a physician-based online survey of willingness to prescribe CR opioids for CNMP. Data collected by the electronic questionnaire were stored on a Microsoft Access database that resided on TAFP's computer server. Survey data were coded and transferred from the Access database to an SPSS 13.0 (SPSS, 2005) statistical package software program.

Cronbach's alpha was utilized to test the reliability of scales used in the survey instrument. Based upon a review of the literature, a Cronbach's alpha at $\alpha = 0.6$ was considered acceptable for this study (Edwards *et al.*, 2001).

Descriptive Analyses

Descriptive statistical analyses were conducted using frequency distributions, means, and standard deviations to describe the respondent population and to identify trends or data abnormalities among study variables (i.e., amount of continuing education, board certification, gender, patients with CNMP, practice location, practice type, race/ethnicity, and years of practice experience). Means and standard deviations were obtained for direct and indirect measures of the TPB constructs of attitude (A_o), subjective norm (SN), and perceived behavioral control (PBC), along with willingness, recent past behavior (RPB), and continuing medical education (CME) variables.

T-Test Analyses

T-Tests were used to assess differences between means among physicians willing to prescribe CR opioids and those who are not willing with regards to significant predictors of A_o, SN, and PBC. Anchors utilized in the semantic scale used to assess willingness ranged from -3 (extremely unwilling) to +3 (extremely willing). To conduct the t-test analysis, willingness was dichotomized as willing and unwilling. Physician respondents who were willing to prescribe CR opioids to treat moderate to severe CNMP patients had a score ranging between +1 (somewhat willing) to +3 (very willing) on the 7-point bipolar semantic differential scale. Non-willing respondents had a score ranging between -1 (somewhat unwilling) to -3 (extremely unwilling). Responders who indicated 0 (i.e., neutral) were not included in the t-test analyses. T-Tests were conducted to evaluate differences among physicians who had received CME education in the past three years (dichotomous variable) with regards to willingness (continuous variable). T-Tests were also conducted to assess the differences between CME and attitudes (continuous variable). Additionally, T-tests were used to evaluate differences between means among men and women with regards to the indirect/direct TPB constructs (A_o, SN, PBC, and willingness).

Analysis of Variance (ANOVA)

ANOVA was conducted to assess differences between the means of the TPB constructs (A_o, SN, PBC, and willingness) and for each non-dichotomous categorical variable (i.e., geographic location, physician ethnicity, and type of practice). ANOVA was conducted for both direct and indirect measure variables.

Correlational Analyses

A correlation analysis was conducted to determine if a significant association existsed between years of physician experience and the direct/indirect TPB constructs (A_o, SN, PBC, and willingness) and RPB.

Multiple Regression Analyses

A multivariate analysis was conducted to determine if the TPB constructs were significant predictors of willingness. The willingness variable was regressed onto the direct/indirect measures of A_o, SN, PBC, and the RPB variable to determine if they were significant predictors of physician willingness to prescribe CR opioids to patients with moderate to severe CNMP. An F-Test was conducted to assess incremental changes in R^2.

4.6 Regression Model

The primary goal of this study was to identify the predictor variables using constructs of the TPB and recent past behavior to predict Texas family physicians' willingness to prescribe CR opioids to patients with moderate to severe CNMP. This was done by developing a multiple regression model based on the dimensions of the direct and indirect TPB constructs (A_o, SN, PBC, willingness), and RPB. The purpose of this model was to predict variable Y, with maximum accuracy, from a linear combination of independent variables (Tabachnick& Fidell, 2001). This study used the following regression model for both indirect and direct TPB measures:

$$Y = b_1X_1 + b_2X_2 + b_3X_3 + b_4X_4 + E$$

The regression coefficient variable is represented as b_x. The independent variable for attitude (A_o) is represented as X_1, the subjective norm (SN) independent variable is X_2, the perceived behavioral control (PBC) independent variable is X_3, the recent past behavior (RPB) independent variable is X_4, and E represents the residual (or error estimate). Y represents the dependent variable of "physicians' willingness to prescribe CR opioids to patients with moderate to severe CNMP."

4.7 Objectives and Hypotheses Tests

The purpose of this study was to explore the predictive utility of the Theory of Planned Behavior (TPB) in understanding physicians' willingness to prescribe CR opioids to treat patients with moderate to severe CNMP. Table 4.1 illustrates the objectives, hypotheses and statistical tests that were used.

Table 4.1 Study Objectives and Hypotheses Tests

Objectives	Hypotheses	Variables Dependent Variable (DV)/ Independent Variable (IV)	Statistical Test
Objective 1	To explore the utility of the TPB constructs (attitude, subjective norm, perceived behavioral control) and the predictive strength of each TPB component in predicting family physicians' willingness to prescribe CR opioids to treat patients with moderate to severe CNMP.		
	H1 Attitude (A_o), subjective norm (SN), and perceived behavioral control (PBC) constructs will explain a significant amount of variance in physicians' willingness to prescribe CR opioids to patients with moderate to severe CNMP.	DV= Willingness IV= Direct measure of A_o IV= Direct measure of SN IV= Direct measure of PBC IV= Indirect measure of A_o (***b**,**e**, **b*** x ***e***) IV= Indirect measure of SN (***n**,**m***, ***n*** x ***m***) IV= Indirect measure of PBC (***c***, ***p***, ***c** x **p***)	<u>Direct measures</u> : Multiple Regression; R^2 F-Test <u>Indirect measures</u>: Multiple Regression; R^2 F-Test
	H2 Favorable attitudes will be a positive and significant predictor of willingness to prescribe CR opioids to patients with moderate to severe CNMP, while controlling for subjective norm and perceived behavioral control.	DV= Willingness IV = Direct measure of A_o IV = Indirect measure of A_o (***b**,**e**, **b*** x ***e***)	
	H3 Social norms supporting the prescribing of CR opioids to patients with moderate to severe CNMP will be a positive and significant predictor of willingness to prescribe, while controlling for attitude and perceived behavioral control.	DV= Willingness IV = Direct measure of SN IV = Indirect measures of SN (***n**,**m***, ***n*** x ***m***)	
	H4 Strong perceptions of behavioral control will be a positive and significant predictor of willingness to prescribe CR opioids to patients with moderate to severe CNMP, while controlling for attitude and subjective norm.	DV= Willingness IV = Direct measure of PBC IV = Indirect measure of PBC(***c***, ***p***, ***c** x **p***)	

A_o= Attitudes, SN= Subjective Norms, PBC= Perceived Behavioral Control; Belief-based measures: ***b***= behavioral beliefs, ***e***= outcome evaluation, ***b** x **e*** = indirect A_o, ***n***= normative belief, ***m***= motivation to comply, ***n** x **m***= indirect SN, ***c***= control belief, ***p***= perceived power, ***c** x **p*** = indirect PBC

Objectives	Table 4.1 (continued) Hypotheses	Variables Dependent Variable (DV)/ Independent Variable (IV)	Statistical Test
Objective 2	To determine if the perceived behavioral control construct adds to the prediction of family physicians' willingness to prescribe CR opioids to patients with moderate to severe CNMP beyond the attitude and subjective norm constructs.		
	H5 The perceived behavioral control construct will significantly increase the explanatory power of the regression model compared to only using attitude and subjective norm to explain family physicians' willingness to prescribe CR opioids to patients with moderate to severe CNMP.	DV= Willingness IVs= Direct measures of A_o, SN, and PBC IVs= Indirect measures of A_o ,SN,and PBC	<u>Direct measures</u> Hierarchical Regression; R^2 F-Test <u>Indirect measures</u> Hierarchical Regression; R^2 F-Test
Objective 3	To determine if the recent past behavior (RPB) construct adds to the prediction of family physicians' willingness to prescribe CR opioids to patients with moderate to severe CNMP (beyond the TPB constructs).		
	H6 The recent past behavior construct will significantly increase the explanatory power of the regression model compared to only using the TPB constructs to explain physicians' willingness to prescribe CR opioids to treat moderate to severe CNMP patients.	DV= Willingness IVs= Direct measures of A_o, SN, PBC, and RPB IVs= Indirect measures of A_o ,SN, PBC, and RPB	<u>Direct measures</u>: Hierarchical Regression; R^2 F-Test <u>Indirect measures</u>: Hierarchical Regression; R^2 F-Test
Objective 4	To determine if the willingness and attitude toward prescribing CR opioids to patients with moderate to severe CNMP differs by exposure to continuing education (CE) in pain management.		
	H7 Physicians who have received CE in pain management will be more willing to prescribe CR opioids to moderate to severe CNMP patients versus physicians who have not received CE.	DV= Willingness IV = CE	<u>Direct measures</u>: T-test <u>Indirect measures</u>: T-test
	H8 Physicians who have received CE in pain management will have more favorable attitudes toward prescribing CR opioids to patients with moderate to severe CNMP versus physicians who have not received CE.	DV= Direct/Indirect measures of A_o IV = CE	<u>Direct measures</u>: T-test <u>Indirect measures</u>: T-test

A_o= Attitudes, SN= Subjective Norms, PBC= Perceived Behavioral Control; RPB= Recent Past Behavior, CE= Continuing education; Belief-based measures: ***b***= behavioral beliefs, ***e***= outcome evaluation, ***b** x **e*** = indirect A_o, ***n***= normative belief, ***m***= motivation to comply, ***n** x **m***= indirect SN, ***c***= control belief, ***p***= perceived power, ***c** x **p*** = indirect PBC

Table 4.1 (continued)

Objectives	**Hypotheses**	**Variables Dependent Variable (DV)/ Independent Variable (IV)**	**Statistical Test**
Objective 5	To determine if family physicians' attitude, subjective norm, or perceived behavioral control toward prescribing CR opioids to patients with moderate to severe CNMP differs by geography.		
	H9 Family physicians that practice in suburban areas will have a significantly more favorable attitude toward prescribing CR opioids to patients with moderate to severe CNMP versus family physicians who practice in rural, suburban, or urban areas.	DVs= Direct/Indirect measures of A_o IV = Geography	Direct measures: ANOVA Indirect measures: ANOVA
	H10 Family physicians that practice in suburban areas will have significantly more favorable subjective norms supporting the prescribing CR opioids to patients with moderate to severe CNMP versus family physicians who practice in rural, suburban, or urban areas.	DVs= Direct/Indirect measures of SN IV = Geography	Direct measures: ANOVA Indirect measures: ANOVA
	H11 Family physicians that practice in suburban areas will have a significantly stronger perception of behavioral control in prescribing CR opioids to patients with moderate to severe CNMP versus family physicians who practice in rural, suburban, or urban areas.	DV= Direct/Indirect measures of PBC IV = Geography	Direct measures: ANOVA Indirect measures: ANOVA
Objective 6	To determine if family physicians' attitude, subjective norm, or perceived behavioral control toward prescribing CR opioids to patients with moderate to severe CNMP differs by physician demographics and practice characteristics.		
	H12 There is no difference in physicians' attitudes toward prescribing CR opioids to moderate to severe CNMP patients between male and female physicians.	DVs= Direct/Indirect measures of A_o IV = Gender	Direct measures: T-test Indirect measures: T-test
	H13 There is no difference in physicians' subjective norm when prescribing CR opioids to moderate to severe CNMP patients between male and female physicians.	DVs= Direct/Indirect measures of SN IV = Gender	Direct measures: T-test Indirect measures: T-test
	H14 There is no difference in physicians' perceived behavioral control over prescribing CR opioids to moderate to severe CNMP patients between male and female physicians.	DV= Direct/Indirect measures of PBC IV = Gender	Direct measures: T-test Indirect measures: T-test

A_o= Attitudes, SN= Subjective Norms, PBC= Perceived Behavioral Control; Belief-based measures: ***b***= behavioral beliefs, ***e***= outcome evaluation, ***b x e*** = indirect A_o, ***n***= normative belief, ***m***= motivation to comply, ***n x m***= indirect SN, ***c***= control belief, ***p***= perceived power, ***c x p*** = indirect PBC

Table 4.1 (continued)

Objectives	Hypotheses	Variables Dependent Variable (DV)/ Independent Variable (IV)	Statistical Test
Objective 6	**H15** There is no difference in physicians' attitudes toward prescribing CR opioids to moderate to severe CNMP patients and physicians years of experience	DVs= Direct/Indirect measures of A_o IV= Years of experience	<u>Direct measures</u>: Correlation <u>Indirect measures</u>: Correlation
	H16 There is no difference in physicians' subjective norm when prescribing CR opioids to moderate to severe CNMP patients and physicians years of experience	DVs= Direct/Indirect measures of SN IV= Years of experience	<u>Direct measures</u>: Correlation <u>Indirect measures</u>: Correlation
	H17 There is no difference in physicians' perceived behavioral control over prescribing CR opioids to moderate to severe CNMP patients and physicians years of experience	DV= Direct/Indirect measures of PBC IV= Years of experience	<u>Direct measures</u>: Correlation <u>Indirect measures</u>: Correlation
	H18 There is no difference in physicians' attitudes toward prescribing CR opioids to moderate to severe CNMP patients and physician ethnicity.	DVs= Direct/Indirect measures of A_o IV = Physician ethnicity	<u>Direct measures</u>: ANOVA <u>Indirect measures</u>: ANOVA
	H19 There is no difference in physicians' subjective norm when prescribing CR opioids to moderate to severe CNMP patients and physician ethnicity.	DVs= Direct/Indirect measures of SN IV = Physician ethnicity	<u>Direct measures</u>: ANOVA <u>Indirect measures</u>: ANOVA
	H20 There is no difference in physicians' perceived behavioral control over prescribing CR opioids to moderate to severe CNMP patients and physician ethnicity.	DVs= Direct/Indirect measures of A_o IV = Physician ethnicity	<u>Direct measures</u>: ANOVA <u>Indirect measures</u>: ANOVA
	H21 There is no difference in physicians' attitudes toward prescribing CR opioids to moderate to severe CNMP patients and type of physician practice.	DV= Direct/Indirect measures of PBC IV = Type of practice	<u>Direct measures</u>: ANOVA <u>Indirect measures</u>: ANOVA
	H22 There is no difference in physicians' subjective norm when prescribing CR opioids to moderate to severe CNMP patients and type of physician practice.	DVs= Direct/Indirect measures of SN IV = Type of practice	<u>Direct measures</u>: ANOVA <u>Indirect measures</u>: ANOVA
	H23 There is no difference in physicians' perceived behavioral control over prescribing CR opioids to moderate to severe CNMP patients and type of physician practice.	DV= Direct/Indirect measures of PBC IV = Type of practice	<u>Direct measures</u>: ANOVA <u>Indirect measures</u>: ANOVA

A_o= Attitudes, SN= Subjective Norms, PBC= Perceived Behavioral Control; Belief-based measures: ***b***= behavioral beliefs, ***e***= outcome evaluation, ***b x e*** = indirect A_o, ***n***= normative belief, ***m***= motivation to comply, ***n x m***= indirect SN, ***c***= control belief, ***p***= perceived power, ***c x p*** = indirect PBC

4.8 Limitations

There are several limitations associated with using multiple regression analysis. As mentioned above, regression analyses were conducted to examine relationships among variables and will not imply that the relationships are causal. Further, it was not known in advance if the study model would satisfy all of the assumptions necessary for regression analysis. Pre-analysis screening procedures were conducted to test the assumption of normality, linearity, and homoscedasticity between predicted scores and errors of prediction. Examination of residuals scatterplots, histograms, and normal probability plots were conducted to detect violations for the assumptions (Tabachnick& Fidell, 2001). It should be recognized that the TPB study model may not have been extremely sensitive to the specific combination of independent variables included in it. The use of regression coefficients (beta weights) may change among different family physician populations when independent variables are added or subtracted from the model. As a result, this instability can make it more difficult to determine the true contributions of the independent and dependent variables (Tabachnick& Fidell, 2001). Further, the addition or removal of independent variables can change the value of R^2, the coefficient of multiple determination, and partial correlations yielded by the model (Tabachnick& Fidell, 2001). Ultimately, each of these factors affect the F-test of significance. In addition, a high multicollinearity found in the multiple regression analysis may also confound the true effects of independent variables being observed.

4.9 Summary

Elements of the research design and methods proposed for this study were reviewed. A description of procedures that were used to develop the instrument items, which include techniques used in elicitation interviews, examination of study variables, and proposed procedures for pretesting the questionnaire were discussed. Methods that were used in instrument distribution, data collection, and data analyses were reviewed. Finally, the objectives, hypotheses, and statistical tests were outlined.

CHAPTER 5: RESULTS

The purpose of this study was to achieve a better understanding of family physicians' willingness to prescribe controlled release opioids (CR opioids) to patients with moderate to severe chronic non-malignant pain (CNMP). The Theory of Planned Behavior (TPB) model was used to examine factors believed to influence physicians' willingness to prescribe. A survey questionnaire was developed and employed to measure the underlying TPB constructs influencing willingness. This chapter presents the following: (1) findings from the three focus groups used to develop the questionnaire instrument; (2) results from the pretest conducted among a small sample of the target population; (3) demographic and practice characteristics of the study sample; (4) results of the direct and indirect TPB measures; and (5) results of the hypotheses tests.

5.1 Focus Group Results

Three focus group interviews were conducted using members of the Texas Academy of Family Physician (TAFP). As previously described in Section 4.2.1, the purpose of conducting focus group interviews was to identify the relevant behavioral, normative and control beliefs that make up physicians' willingness. Data collected from focus group participants were used to develop the belief-based items of the TPB questionnaire instrument.

A total of 15 TAFP members volunteered to participate in focus group interviews. The first focus group took place in Austin, Texas. This focus group was comprised of three family physicians who were attending a TAFP conference. The second focus group took place on day two of the conference and was comprised of six family physicians. The third focus group was comprised of six family physicians who were attending a different TAFP conference held in San Antonio, Texas. The first focus group lasted approximately 30 minutes, the second group lasted 75 minutes and the third focus group lasted 60 minutes. No compensation was given to TAFP members participating in the focus groups. Three sets of questions were used in each focus group; behavioral beliefs, normative beliefs, and control belief questions. Appendix A contains the interview guide used to conduct the focus group. Participants were asked to respond to the following nine focus group questions:

Behavioral Belief Questions

1. What do you think are some of the advantages associated with family physicians (FPs) prescribing CR Opioids to treat patients with moderate to severe CNMP?

2. What do you think are some of the disadvantages associated with FPs prescribing CR Opioids to treat patients with moderate to severe CNMP?

3. Are there any other advantages or disadvantages associated with FPs prescribing CR Opioids to treat patients with moderate to severe CNMP?

Normative Belief Questions

4. Are there any individuals or groups who would approve of FPs prescribing CR-Opioids to treat patients with moderate to severe CNMP?

5. Are there any individuals or groups who would not approve of FPs prescribing CR Opioids to treat patients with moderate to severe CNMP?

6. Are there any other individuals or groups who would or would not approve of FPs prescribing CR Opioids to treat patients with moderate to severe CNMP?

Control Belief Questions

7. What do you think would make it easier for FPs prescribing CR Opioids to treat patients with moderate to severe CNMP?

8. What do you think would make it more difficult for FPs prescribing CR Opioids to treat patients with moderate to severe CNMP?

9. Are there any other factors that you think would make it easier or more difficult for FPs prescribing CR Opioids to treat patients with moderate to severe CNMP?

A content analysis was conducted on focus group responses (Ajzen& Fishbein, 1980). Focus group transcripts were analyzed for emerging themes elicited by the participants. Individual responses to question items were examined, and key words and phrases were grouped into belief categories. Tables 5.1, 5.2, and 5.3 provide a summary of the responses to the nine focus group questions. Frequencies for each of the three belief categories were tabulated and then ranked from highest to lowest modal belief categories.

Behavioral Beliefs

Table 5.1 presents a summary list of behavioral beliefs identified from the focus group interviews of TAFP participants. Based on the three behavioral belief questions (Questions 1-3), a total of 22 belief categories were identified and grouped according to frequency. Focus group results showed that 13 of the 15 physicians interviewed believed that prescribing CR opioids for moderate to severe CNMP might lead to abusive drug behaviors. A total of 13 physicians indicated that additional patient history would be required if CR opioids were prescribed. Other salient behavioral beliefs included lengthy office visits, effectiveness in controlling pain, improvement of patient quality of life, costs compared to short-acting alternatives, ease/difficulty in managing patients on multiple medications and/or co-morbidities, higher possibility of addiction, and regulatory scrutiny.

Table 5.1 Behavioral Belief Items: Content Analysis of Focus Group Responses (N=15)

Questions 1-3: What are the advantages/disadvantages associated with family physicians prescribing CR Opioids to patients with moderate to severe CNMP?

Belief	Responses	Frequency
1	Will lead to abusive drug behaviors (e.g., drug seeking, illicit use, diversion)	13
2	Will require additional patient history	13
3	Will lengthen office visits	9
4	Will be effective in controlling the patients pain	6
5	Will improve the patient's quality of life	6
6	Is less expensive compared to other short-release drugs	4
7	Will make it easier to manage those patients on multiple medications	4
8	Will lead to patient addiction	3
9	Will make it easier to manage patients with co morbidities	3
10	Will lead to increased regulatory scrutiny	3
11	Results in no clear end-point in treating patient's pain	2
12	Will increase my use of patient contracts	2
13	Will cause patients to experience side effects (e.g., constipation, sedation)	2
14	Will increase my legal liability	1
15	Will increase my level of professional satisfaction	1
16	Will cause me to become properly trained in CNMP	1
17	Will cause my patient to become pseudo addicted	1
18	Will increase robbery to my practice	1
19	Will cause my patient to be stigmatized as an aberrant drug user	1
20	Will cause me to seek support from other health specialists	1
21	Will increase the level of support needed from my staff	1
22	Will cause patient tolerance to the medication	1
	Total	**79**

According to the TPB framework, a minimum of five to nine belief items are needed to construct the indirect attitude measure (Ajzen& Fishbein, 1980). For this study, behavioral beliefs reported by at least three or more focus group participants were used (Table 5.1). As a result, 10 of the most frequently mentioned beliefs were selected to construct the behavioral belief-based items used in the questionnaire instrument.

Table 5.2 Normative Beliefs Items: Content Analysis of Focus Group Responses (N=15)

Questions 4-6: Which individuals or groups would/would not approve of FPs prescribing CR Opioids to treat patients with moderate to severe CNMP?

Belief	Responses	Frequency
1	Regulatory Agencies	6
2	Other primary care physician colleagues	3
3	Consumer groups	3
4	Pain specialty physicians	3
5	Patients	3
6	Texas Medical Board	2
7	Other Healthcare Providers and staff	2
8	Community	1
9	Hospice	1
10	Hospital Administrators	1
11	Legislators	1
12	Managed Care Organizations (e.g., insurance, Medicaid, Medicare)	1
13	Media	1
14	Medical Associations (e.g., AAFP, AMA,)	1
15	Patients' relatives	1
	Total	**30**

Normative Beliefs

Focus group participants were asked to list important individuals/groups (i.e., referents) that would approve or disapprove of family physicians using CR opioids to treat patients with moderate to severe CNMP. Table 5.2 provides a summary list of the salient normative beliefs identified from focus group interviews. Based on the three belief questions (Questions 4-6), a total of 15 normative belief categories were identified and grouped according to frequency. The most common normative belief was that regulatory agencies would either approve or disapprove of their prescribing CR opioids for moderate to severe CNMP. Other more frequently identified beliefs included physicians' colleagues, consumer groups, specialists, patients, and other health providers who may approve/disapprove of prescribing CR opioids.

Similar to behavioral beliefs, a minimum of five to nine belief items are required to construct the normative belief-based measure (Ajzen& Fishbein, 1980). For this study, normative beliefs mentioned by two or more focus group participants were included as items in the questionnaire. As a result, seven of the most frequently mentioned referents were used to construct the normative belief scale used in the survey.

Table 5.3 Control Beliefs Items: Content Analysis of Focus Group Responses (N=15)

Questions 7-9: What factors do you think would make it easier/difficult for family physicians to prescribe CR opioids to treat patients with moderate to severe CNMP?

Belief	Responses	Frequency
1	Having more knowledge in pain management	12
2	Access to pain management tools	11
3	Not having to write triplicates prescriptions	6
4	Patients who are on multiple medications	5
5	Complete compensation for services associated w/ prescribing CR opioids	5
6	Access to multidisciplinary teams	3
7	Ready access to patient medical records	3
8	More evidence-based studies	3
9	Patients who have multiple co morbidities	3
10	Less regulatory scrutiny	3
11	More access to other treatment modalities	2
12	Less expensive drugs	2
13	Less legal liability	2
14	Less abuse by patients	1
15	Less addictive drug	1
16	Less drug seeking patients	1
17	Less physical dependence	1
18	More patient education	1
19	More time available for patients	1
20	No clear end-points	1
21	No side effects	1
22	Robbery	1
23	Stigmatization	1
	Total	**71**

Control Beliefs

Focus group participants were asked to list factors that they believed would make it easier or more difficult to prescribe CR opioids to patients with moderate to severe CNMP. Table 5.3 outlines the responses for the modal control beliefs elicited. Based on the three control belief questions asked (Questions 7-9), a total of 23 control belief categories were identified and grouped according to frequency. Results showed 12 of the 15 physicians interviewed believed that having more knowledge in pain management would make it easier for them to prescribe CR opioids to patients with moderate to severe CNMP. A total of 11 physicians indicated that access to pain management tools (e.g., algorithms, protocols, guides, contracts, diagnostic kits) would make it easier to prescribe CR opioids. Six focus group participants indicated that writing triplicates made it more difficult for them to prescribe CR opioids for CNMP. Other control beliefs mentioned included having patients on multiple medications, receiving complete compensation for services associated with prescribing CR opioids, having access to multi-disciplinary teams and patient medical records, availability of more evidence-based studies, patients with co-morbidities, and regulatory scrutiny.

Similar to methods used to select behavioral and normative beliefs, a minimum of five to nine belief items are needed to construct the indirect perceived behavioral control measure. For this study, control beliefs reported by at least three or more focus group participants were used, resulting in 10 belief-based items used in the final questionnaire instrument (Table 5.3).

Table 5.4 Theory of Planned Behavior Questionnaire Items (Summary of Direct and Indirect Items)

Theoretical Concept	Belief Component	Number of items	Questionnaire Item
Willingness		1	1
Attitude (indirect)	Behavioral beliefs	10	2a thru 2j
	Outcome evaluation	10	3a thru 3j
Attitude (direct)		4	4a thru 4d
Subjective Norm (indirect)	Normative beliefs	7	5a thru 5g
	Motivation to comply	7	6a thru 6g
Subjective Norm (direct)		1	7
Perceived Behavioral Control (indirect)	Control beliefs	10	8a thru 8j
	Perceived power	10	9a thru 9j
Perceived Behavioral Control (direct)		2	10 and 11

Table 5.4 gives a breakdown of the number and type of TPB scales used in the questionnaire instrument. One question item was used to assess physicians' willingness to prescribe CR opioids for CNMP. A total of 20 items were used to assess indirect attitude. Four items were used to assess direct attitude. For indirect subjective norm, 14 items were used. One item was used to assess direct subjective norm. A total of 20 items were used for indirect perceived behavioral control and direct perceived behavioral control was assessed using two items.

5.2 Pretesting Survey

The TPB survey was pretested to identify issues that may affect instrument length, face validity, content, clarity, format, and organization. Ten family physicians were invited to participate in pretesting the electronic questionnaire. Physicians were sent a cover letter e-mail that contained a hyperlink to the electronic questionnaire and were instructed to review the online questionnaire for its ease of readability, clarity and relevance of items, and format. Participants also were asked to record the time it took them to complete the survey instrument.

Seven family physicians participated in the pretest. The internal consistency of the instrument was examined. Cronbach's alpha was used to test instrument reliability of the three TPB indirect (belief-based) scales. Alpha coefficients for the indirect attitude (0.73) and perceived behavioral control (0.83) scales were considered adequate (Cronbach, 1951), however the alpha coefficient obtained for indirect subjective norm (0.63) was slightly below adequate. One possible explanation for the low reliability of the subjective norm scale may be attributed to the low number of participants (N=7) used in the pretest. Examination of internal consistency for the direct TPB scales showed acceptable alpha coefficient for direct attitude (0.99) and perceived behavioral control scale (0.73). Cronbach's alpha was not computed for the direct subjective norm scale due to it being only one item.

5.3 Distribution of Survey Response Rates

Of the 2,750 web surveys initially e-mailed on June 27th, 2006 to eligible TAFP members, approximately 150 e-mail addresses bounced back to the TAFP computer server (i.e., non-working or invalid e-mail address). A follow-up e-mail was resent to the TAFP group two weeks later, July 11, 2006. In an effort to further increase the survey response rate, a final e-mail was sent out by the 2006 TAFP Research Chair, on August 10, 2006. A total of five physicians opted out of participating in the survey. The survey enrollment period ended August 23, 2006 (total data collection period was nine weeks). Of the 2,600 presumably valid survey e-mails sent, a total of 267 usable surveys were submitted to the online database, yielding a 10 percent response rate.

5.4 Assessment of Data Normality

Routine pre-analysis screening procedures were conducted to assess the normality of the data. The skewness and kurtosis of each variable was examined to determine how much the distribution among the variables varied from the normal distribution. Curran *et al*. (1996) recommend further examination of distribution when univariate skewness is greater than |2.0| and kurtosis is greater than |7.0|.

Examination of the skewness and kurtosis statistics for each of the variables indicated all TPB variables were within the threshold values for normality except one. The demographic variable "average number of CNMP patients seen per week" (skewness=6.379) exceeded the threshold for non-normality. Further examination of the data revealed outliers among three respondents on this particular item. When the average number of CNMP patients /week variable was collapsed into 6 categories skewness for the ordinal measure was 1.462.

5.5 Assessment of Missing Data

A total of 390 instances of missing data were observed across 77 survey items (N=267 respondents). Further examination of the survey data found that 28.8 percent (N=77) of respondents had at least one missing data value. The rate of missing data did not exceed 4.9 percent for any of the variables.

Table 5.5 Internal Consistency Analysis of Indirect and Direct Item Scales

	Number of Items	Standardized Item Alpha
Indirect Scale (belief-based items)		
Belief-Based Attitude	20	0.79
Belief-Based Subjective Norm	14	0.71
Belief-Based Perceived Behavioral Control	20	0.82
Direct Scale		
Direct Attitude	4	0.95
Direct Subjective Norm	1	N/A*
Direct Perceived Behavioral Control	2	0.56

*Only 1-item used to assess the construct

5.6 Internal Consistency

Cronbach's alpha was used to assess the internal consistency of the indirect and direct TPB measurement scales (variables). All three indirect measurement scales demonstrated a composite alpha coefficient score exceeding the 0.60 threshold (Edwards *et al.*, 2001). Table 5.5 illustrates the reliability coefficients for each scale. Internal consistency for the direct attitude scale indicated a high alpha coefficient (0.95), however the alpha coefficient obtained for the direct perceived behavioral control scale (0.56) was slightly below adequate. One possible explanation for the low reliability of the perceived behavioral control scale may be attributed to the low number of items used to assess the construct. Cronbach's alpha was not computed for the direct subjective norm scale due to it being only one item.

Table 5.6 Demographic Characteristics: Gender, Years Experience, and Ethnicity

Variable	N (%)	Mean	Standard Deviation	Minimum Value	Maximum Value
Gender[a]					
Male	165 (61.8)				
Female	98 (36.7)				
Missing	4 (1.5)				
Years experience[b]	262 (98.1)	16.5	10.7	1	57
Missing	5 (1.9)				
Ethnicity[c]					
White/European American	194 (72.7)				
Latino/Latin American Hispanic	31 (11.6)				
Asian or Pacific Islander	15 (5.6)				
African-American/Black	5 (1.9)				
Native American/Indigenous Peoples	0 (0.0)				
Other	16 (6.0)				
Missing	6 (2.2)				

[a]4 physicians failed to indicate gender (N=263)
[b]5 physicians failed to indicate years experience (N=262)
[c]6 physicians failed to indicate ethnicity (N=261)

5.7 Demographics and Practice Characteristics

Table 5.6 illustrates respondent demographics. Approximately 62 percent of the physician's responding to the survey were male. The average number of years of practice experience among family physician respondents was 16.5 years (median=16, SD=10.7). The majority of respondents were White/European American (72.7%).

Table 5.7 Practice Characteristics: Type of practice, Practice location, Number of CNMP patients seen per week

Variable	N (%)	Mean	Standard Deviation	Minimum Value	Maximum Value
Type of Primary Practice[a]					
Physician Group	93 (34.8)				
Solo Practice	54 (20.2)				
Hospital or Clinical Institution	41 (15.4)				
Partnership Practice	40 (15.0)				
Managed Care	5 (1.9)				
Other	27 (10.1)				
Missing	7 (2.6)				
Location of Primary Practice[b]					
Urban	93 (34.8)				
Suburban	92 (34.5)				
Rural	75 (28.1)				
Missing	7 (2.6)				
Number of CNMP Patients seen per week[b]	254 (95.1)	7.9	15.5	0	150
Missing	13 (4.9)				

[a]7 physicians failed to indicate type of primary practice (N=260)
[b]7 physicians failed to indicate location of primary (N=260)
[c]13 physicians failed to indicate number of patients seen per week (N=254)

Table 5.7 depicts the practice characteristics of family physician respondents. Over one-third (34.8%) of respondents reported “physician group” as their primary type of practice while 20 percent indicated having a “solo practice.” Responses to primary practice location showed that 34.8 percent of physicians reported their primary practice being located in an “urban” setting, while 34.5 percent practiced in a “suburban” setting, and 28.1 percent were located in a “rural” setting.

Table 5.8 Number of Chronic Non-Malignant Pain (CNMP) patients seen per week

Number of CNMP Patients seen per week	Frequency [a]	Valid Percent	Cumulative Percent
Zero	20	8.1%	8.1%
1 to 5	143	57.9%	66.0%
6 to 10	42	17.0%	83.0%
11 to 15	21	8.5%	91.5%
16 to 20	9	3.6%	95.1%
> 21	12	4.9%	100.0%
Total	**247**	**100%**	
Missing	20	7.5%	

[a]20 physicians failed to complete this variable

Respondents reported seeing an average of eight CNMP patients per week (median=5, SD=15.5). The average number of CNMP patients seen by family physicians ranged from zero to 150 per week. As previously mentioned, a skewed distribution was observed for this variable (skewness=6.379). Results of this non-normal distribution may be due to the influence of three outlier and several extreme values observed among a small group of physician respondents treating a substantial number of CNMP patients. For example, one physician reported seeing an average of 150 CNMP patients per week, while two other respondents saw an average of 120 patients per week. When the variable was collapsed into six ordinal categories the skewness for this variable was 1.46. Table 5.8 illustrates the number of CNMP patients seen by family physicians grouped by categories. Examination of the categorical data shows that approximately 66 percent of physician respondents reported seeing an average of five or less CNMP patients per week while 4.9 percent of physician respondents reported seeing at least an average of 21 or more CNMP patients per week.

Family physicians were asked how often they prescribed CR opioids to patients with moderate to severe CNMP within the last month (Table 5.9). Using an ordinal measurement scale (1=Never to 6=Always), 23 percent of respondents indicated that they "never" prescribed CR opioids to patients while two percent indicated that they always prescribed CR opioids. To test the reliability of the item measure, a second variable was used to assess how often respondents prescribed CR opioids to CNMP patients. Results to the second item measure showed that 17 percent of physicians indicated that they "never" prescribed CR opioids and none of the respondents indicated they always prescribed CR opioids for moderate to severe CNMP. Cronbach's alpha showed an acceptable reliability estimate (0.75) between the two variables. The second variable was used as the direct measure for the recent past behavior scale (a component of the TPB model). Further analysis of this variable will be discussed in Section 5.10.1.

Table 5.9 Family physicians' past prescribing behavior of CR opioids for moderate to severe CNMP

Respondents were asked to rate the following recent past behavior questions:

Question 12: "How often have you prescribed long-acting opioids to patients with moderate to severe CNMP in the last month?"

Question 20: "How often do you prescribe long-acting opioids to patients with moderate to severe CNMP?"

				Frequency Distribution of Responses (%)						
	N	**Mean**	**SD**	**Never (1)**	**(2)**	**(3)**	**(4)**	**(5)**	**(6)**	**Always (7)**
Q12. Prescribe CR opioids in the last month?	264[a]	3.50	1.91	22.7%	17.0 %	7.6%	14.8 %	18.2%	17.4%	2.3%

				Never (1)	**Sometimes (2)**	**About Half the Time (3)**	**Most of the Time (4)**	**Always (6)**
Q20. Prescribe CR opioids (in general)	262[b]	2.32	0.94	17.2%	49.2%	17.6%	16.0%	0.0%

[a]3 physicians failed to answer (N=264)
[b]5 physicians failed to answer (N=262)

In terms of generalizability of demographic data, a comparison of demographic and practice characteristics of the study sample and population data, obtained from the 2006 TAFP membership database, showed the characteristics of physician respondents to be fairly similar to that of the TAFP population (Appendix E). Some dissimilarities were noted. A higher proportion of physicians practicing in rural areas responded to the survey. Physician respondents with solo practices were underrepresented in the survey compared to the actual 2006 TAFP membership population.

5.8 Continuing Medical Education

The survey asked family physicians three questions regarding their views toward exposure to continuing medical education (CME) in chronic pain management (Table 5.10). Of the 262 family physicians responding to the following CME question: "Have you received any CME in chronic pain management in the last three years?" approximately 71 percent (N=190) of respondents reported receiving this type of continuing education in the last three years. This variable was used in assessing physicians' willingness and attitudes (will be discussed in Section 5.10). Table 5.10 shows the mean frequency distribution of respondents' views toward access to CME programs in chronic pain management.

Table 5.10 Family physicians' views toward continuing medical education (CME) in chronic pain management

Respondents were asked to rate the following CME questions:

Question 22: "I feel that I have access to CME courses in chronic pain management (CPM)."
Question 23: "How likely would you be to attend CPM CME activities in the next year?"
Question 24: "How likely would you be to attend CPM CME activities offered by TAFP?"

				Frequency Distribution of Responses (%)						
	N	**Mean**	**SD**	**Strongly Disagree (-3)**	**Somewhat Disagree (-2)**	**Slightly Disagree (-1)**	**Neutral (0)**	**Slightly Agree (+1)**	**Somewhat Agree (+2)**	**Strongly Agree (+3)**
Q22. Access to CME	263[a]	1.24	1.35	0.8%	3.4%	10.3%	6.5%	31.2%	31.6%	16.3%
				Extremely Unlikely (-3)	**Quite Unlikely (-2)**	**Slightly Unlikely (-1)**	**Neutral (0)**	**Slightly Likely (+1)**	**Quite Likely (+2)**	**Extremely Likely (+3)**
Q23. CME next year	262[b]	0.65	1.51	4.6%	8.0%	9.2%	9.9%	38.9%	22.9%	6.5%
Q24. CME by TAFP	263[c]	0.89	1.48	3.4%	6.8%	8.7%	6.1%	36.1%	30.4%	8.4%

[a]4 physicians failed to answer (N=263)
[b]5 physicians failed to answer (N=262)
[c]4 physicians failed to answer (N=263)

Overall, 79 percent of physician respondents agreed (+1="slightly agree" to +3="strongly agree") with the statement that they felt they had access to CME courses in chronic pain management (Mean=1.24, SD=1.35, range -3 to +3). However, 14.5 percent of family physicians disagreed with the statement. The next set of CME questions asked if family physicians would attend CME in chronic pain management in the next year or would attend if it was offered by the Texas Academy of Family Physicians (TAFP). Of the 262 respondents, 68.3 percent indicated they were likely to attend a CME activity in the next year. Three-fourths of physician respondents indicated that they would likely attend chronic pain management activities offered by TAFP (Refer to Table 5.10).

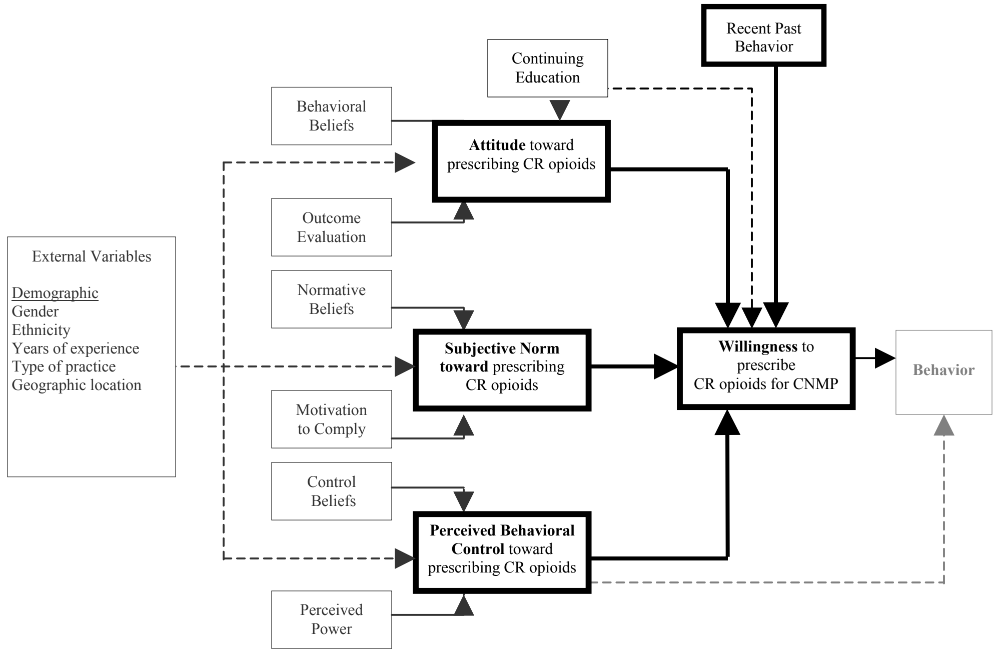


Figure 5.1 TPB Study Model: Direct Measure Constructs

5.9 Constructs of the Theory of Planned Behavior

The questionnaire measured the TPB constructs willingness, attitude, subjective norm, and perceived behavioral control. For the purpose of this study, the willingness construct was assessed using a direct measure. The attitude, subjective norm, and perceived behavioral control constructs were measured using both direct and indirect (belief-based) measures. The TPB model also included the additional predictor variable recent past behavior— RPB (variables was a direct measure).

5.9.1 Direct Measures

Direct measures of willingness, attitude, subjective norm, and perceived behavioral control toward prescribing CR opioids to CNMP patients were developed from a review of the literature and Fishbein and Ajzen's TPB model (Figure 5.1).

The TPB direct measure variables were measured using a 7-point Likert scale (each question-item anchored by -3 to +3). Willingness was measured using one question- item, direct attitude was measured using four items, direct subjective norm was measured with one item, and perceived behavioral control was measured using two items.

The recent past behavior variable was measured with one question item using a 5-point Likert scale (anchored by 0=never to 5=always).

Table 5.11 Willingness to prescribe CR opioids to chronic non-malignant pain patients

Respondents were asked to rate the following willingness question based on 1 item:

Question: "I am willing to prescribe long-acting opioids to treat patients with moderate to severe chronic non-malignant pain (CNMP)."

				Frequency Distribution of Responses (%)						
				Extremely Unlikely	Quite Unlikely	Somewhat Unlikely	Neither Likely nor Unlikely	Somewhat Likely	Quite Likely	Extremely Likely
Item	**N**	**Mean**	**SD**	**(-3)**	**(-2)**	**(-1)**	**(0)**	**(+1)**	**(+2)**	**(+3)**
Q1. Willingness	267 [a]	0.47	1.71	5.6%	12.0%	15.4%	4.5%	28.8%	26.6%	7.1%

[a] All physician respondents answered this question item (N=267)

Direct Measure of Willingness

Direct willingness was measured with a 1-item question. Table 5.11 shows the mean frequency and distribution of willingness. The mean willingness score was 0.47 (SD=1.71, range -3 to +3), indicating that overall, physician respondents were slightly willing to prescribe CR opioids to patients with moderate to severe CNMP. Out of the 267 family physicians who responded to the question, one-third of responses (N=88) were between -1 and -3, indicating that 33 percent of respondents were unwilling to prescribe CR opioids to CNMP patients. Only 5.6 percent of respondents indicated that they were extremely unwilling (-3) to prescribe CR opioids to their CNMP patients. Overall, 62.5 percent of physicians indicated that they were likely (+1 to +3) to prescribe CR opioids.

Table 5.12 Direct attitudes toward prescribing CR opioids to chronic non-malignant pain patients

Respondents were asked to rate the following attitude question based on 5 items:

Question: "I feel that prescribing long-acting opiates to patients with moderate to severe chronic non-malignant pain is..."

				Frequency Distribution of Responses (%)						
Question Items	N[a]	Mean	SD	Very Bad (-3)	(-2)	(-1)	Neutral (0)	(+1)	(+2)	Very Good (+3)
Q1. Bad/Good	265	0.72	1.38	1.5%	6.4%	7.9%	26.0%	27.9%	20.8%	9.4%
				Very Harmful (-3)	(-2)	(-1)	Neutral (0)	(+1)	(+2)	Very Beneficial (+3)
Q2. Harm/Benefit	265	0.86	1.41	1.9%	5.3%	9.4%	17.7%	30.9%	23.8%	10.9%
				Very Useless (-3)	(-2)	(-1)	Neutral (0)	(+1)	(+2)	Very Useful (+3)
Q3. Useless/ Useful	265	1.00	1.35	1.5%	4.9%	6.8%	15.1%	33.6%	26.8%	11.3%
				Very Foolish (-3)	(-2)	(-1)	Neutral (0)	(+1)	(+2)	Very Wise (+3)
Q4. Foolish/Wise	264	0.52	1.44	3.8%	6.4%	7.6%	31.4%	25.0%	18.2%	7.6%
				Very Useless (-3)	(-2)	(-1)	Neutral (0)	(+1)	(+2)	Very Useful (+3)
Q5. Worthless/ Valuable	264	0.88	1.39	3.0%	3.0%	7.2%	21.2%	31.4%	23.1%	11.0%
Scale Total	**263**	**3.96[b]**	**6.33**							

[a] Respondents answering each question-item ranged from 264 to 265 (Total survey respondents N=267)
[b] Scale total indicates the Composite Score for Direct Attitude

Direct Measure of Attitudes

Table 5.12 shows the mean frequency and distribution of direct attitudes. Physicians' direct attitudes were measured with five question-items. Each item used a 7-point bipolar semantic differential scale with the following anchors: bad/good, harmful/ beneficial, useless/useful, foolish/wise, and worthless/valuable. The mean scale total (i.e., composite score) for direct attitude was 3.96 (SD=6.33, range -15 to +15), indicating that physicians held an overall favorable attitude toward prescribing CR opioids to their CNMP patients. Respondents mean item scores (range -3 to +3) for direct attitude were between 0.72 for the good/bad item, 0.86 for harmful/ beneficial, 1.00 for useless/useful, 0.52 for foolish/wise, and 0.88 for worthless/valuable.

Table 5.13 Direct subjective norm toward prescribing CR opioids to chronic non-malignant pain patients

Respondents were asked to rate the following subjective norm question based on 1 item:

Question: "If I prescribe long-acting opioids for patients with moderate to severe CNMP, most people who are important to me would approve?"

				Frequency Distribution of Responses (%)						
Question Item	**N**	**Mean**	**SD**	**Strongly Disagree (-3)**	**Somewhat Disagree (-2)**	**Slightly Disagree (-1)**	**Neutral (0)**	**Slightly Agree (+1)**	**Somewhat Agree (+2)**	**Strongly Agree (+3)**
Q1.	264[a]	1.03	1.52	1.9%	6.4%	10.2%	11.4%	22.3%	33.7%	14.0%

[a] Physician respondents answered this question item (N=264)

Direct Measure of Subjective Norm

Direct subjective norm was measured with a 1-item question (using a 7-point bipolar scale). Table 5.13 shows the mean frequency and distribution of direct subjective norm. The mean composite score for direct subjective norm was 1.03 (SD=1.52, range -3 to +3). Out of the 264 respondents, 70 percent (N=185) of physician respondents "slightly agreed" to "strongly agreed" with the statement, "If I prescribe long-acting opioids for patients with moderate to severe CNMP, most people who are important to me would approve." Interpretation of the direct subjective norm score implies that a weak positive social pressure may influence physicians' decisions to prescribe CR opioids to their CNMP patients.

Table 5.14 Direct perceived behavioral control over prescribing CR opioids to chronic non-malignant pain patients

Respondents were asked to rate the following two perceived behavioral control question items:

Question 1: "It is easy for me to prescribe long-acting opioids to treat patients with moderate to severe CNMP."

Question 2: "I have complete control over whether or not I will prescribe long-acting opioids for patients with moderate to severe CNMP."

				Frequency Distribution of Responses (%)						
Question Item	**N [a]**	**Mean**	**SD**	**Strongly Disagree (-3)**	**Somewhat Disagree (-2)**	**Slightly Disagree (-1)**	**Neutral (0)**	**Slightly Agree (+1)**	**Somewhat Agree (+2)**	**Strongly Agree (+3)**
Q1. Easy for me to Rx CR opioids	260	0.17	1.99	14.6%	11.5%	13.5%	8.1%	16.9%	25.8%	9.6%
Q2. Complete control over Rx CR opioids	263	1.30	1.78	4.9%	6.8%	7.2%	5.7%	14.4%	31.2%	29.7%
Scale Total	**259**	**1.45 [b]**	**3.12**	----	----	----	----	----	----	----

[a] Respondents answering each question-item ranged from 260 to 263 (Total survey respondents N=267)
[b] Scale total indicates the Composite Score for Direct Perceived Behavioral Control

Direct Measure of Perceived Behavioral Control

Two question-items were used to measure physicians' direct perceived behavioral control (PBC). Each question-item used a 7-point bipolar scale, ranging from -3= "strongly disagree" to +3="strongly agree." Table 5.14 shows the mean frequencies and distributions of each item and the overall direct PBC mean score. The mean composite score for direct PBC was 1.45 (SD=3.12, range -9 to +9), indicating that physicians felt they had a slight level of control over prescribing CR opioids to patients with moderate to severe CNMP. The mean responses to the first question-item "It is easy for me to prescribe long-acting opioids to treat patients with moderate to severe CNMP," was 0.17 (SD=1.99, range -3 to +3). Of the 260 physicians responding to this item, 52.3 percent (N=136) of respondents slightly agreed to strongly agreed with the statement. Conversely, about 40 percent of respondents disagreed with the statement. Responses to the second direct PBC question-item, "I have complete control over whether or not I will prescribe long-acting opioids for patients with moderate to severe CNMP," showed a mean of 1.3 (SD=1,78, range -3 to +3). Over three-fourths of the respondents (N=197) felt they had complete control over prescribing CR opioids to their CNMP patients while 18.9 percent of physicians disagreed with the statement.

Table 5.15 Direct recent past behavior in prescribing CR opioids to chronic non-malignant pain patients

Respondents were asked to rate the following recent past behavior question based on 1 item:

Question: **"**How often do you prescribe CR opioids to patients with moderate to severe CNMP?"

				Frequency Distribution of Responses (%)				
Question Item	**N**	**Mean**	**SD**	**Never (+1)**	**Sometimes (+2)**	**About Half the Time (+3)**	**Most of the Time (+4)**	**Always (+5)**
Q1.	262	2.32	0.94	17.2%	49.2%	17.6%	16.0%	0.0%

[a] Physician respondents answered this question item (N=262)

Direct Measure of Recent Past Behavior Construct

Direct recent past behavior (RPB) was measured with a 1-item question using a 5-point unipolar Likert scale (ranging from 1= "never" to +5= "always"). Table 5.15 shows the mean frequencies and distributions of each item and the overall direct RPB mean score. The mean RPB score was 2.32 (SD=0.94), indicating that overall, physician respondents prescribed CR opioids to CNMP patients sometimes to about half the time. Out of the 262 valid responses, one-third of physicians (N=88) indicated that they prescribed CR opioids to their CNMP patients at least half the time. However, approximately 17.2 percent of respondents indicated that they never prescribed CR opioids to their moderate to severe CNMP patients.

Continuing Medical Education

One question-item was used to measure physicians' direct continuing medical education (CME) in chronic pain management. This question item was measured as a dichotomous variable. Results for the CME measure showed that approximately 71 percent (N=190) of the 262 physicians respondents reported receiving CME in chronic pain management in the last three years.

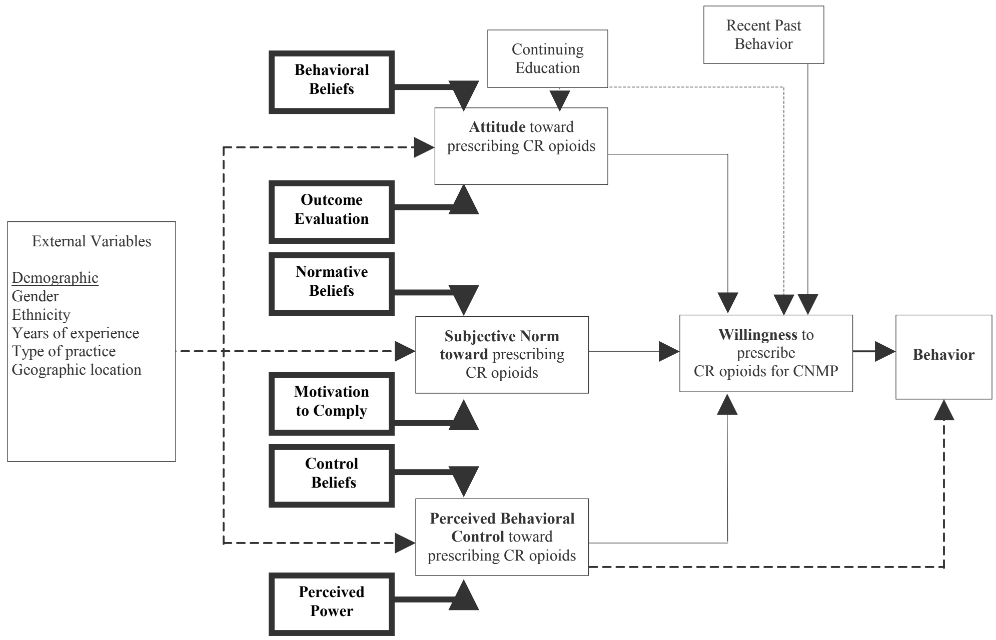


Figure 5.2 TPB Study Model: Indirect (Belief-Based) Measure Constructs

5.9.2 Indirect (Belief-Based) Measures

The indirect measures of attitude, subjective norm, and perceived behavioral control were developed from salient belief data gathered during focus group interviews (Figure 5.2). All belief-based variables utilized in the questionnaire instrument were measured using a 7-point Likert scale (question-items used were either anchored by -3 to +3 or 1 to +7). Belief-based attitude was measured using a total of 20 question-items, belief-based subjective norm was measured utilizing 14 items, and belief-based perceived behavioral was measured using 20 items. Composite scores were calculated for each of the belief-based measure constructs.

Belief-based Attitudes

The belief-based attitude measure is comprised of two components, behavioral beliefs and outcome evaluations. Table 5.16 illustrates the mean frequency and distribution of the behavioral beliefs (b_i). For this belief component, respondents were asked to rate the likelihood of 10 separate belief items ($b_{1\text{-}10}$) occurring if they prescribed CR opioids to patients with moderate to severe CNMP.

Next, outcome evaluation (e_i) was calculated for each of the behavioral-belief items. Family physicians were asked to rate how "good" or "bad" the consequences of each belief-item would be if they prescribed CR opioids to patients with moderate to severe CNMP. Table 5.17 illustrates the mean frequency and distribution of outcome evaluation (e_{1-10}) items which make up indirect attitude.

Table 5.16 Behavioral beliefs of physicians toward prescribing CR opioids to patients with chronic non-malignant pain

Respondents were asked to rate the following indirect attitude question based on 10 behavioral-belief items:

Question: "<u>How likely</u> do you think the following outcomes will occur if you prescribe long-acting opioids to patients with moderate to severe CNMP?"

				Frequency Distribution of Responses (%)[a]						
Behavioral-Belief Items (b_i)	**N[b]**	**Mean**	**SD**	**Extremely Unlikely (-3)**	**(-2)**	**(-1)**	**Neutral (0)**	**(+1)**	**(+2)**	**Extremely Likely (+3)**
1. Leads to abusive behaviors	265	-0.09	1.51	3.4	21.1	16.2	15.5	31.3	9.1	3.4
2. Require additional patient history	263	1.75	1.20	0.8	2.3	2.3	6.5	20.2	39.9	28.1
3. Lengthen patient office visits	266	0.97	1.52	1.1	6.8	10.9	16.5	19.9	29.3	15.4
4. Effective in controlling pain	266	1.33	1.20	0.8	2.3	6.4	9.8	25.2	45.5	10.2
5. Improve patient quality-of-life	265	1.28	1.28	0.8	4.2	5.3	10.2	27.9	39.2	12.5
6. Less expensive than short-acting opioids	266	0.12	1.46	4.9	9.4	15.4	33.5	16.5	16.5	3.8
7. More difficult to manage patients on multiple Rxs	266	-0.05	1.48	2.6	16.5	24.1	16.2	24.4	12.8	3.4
8. More difficult to manage patients with co-morbidities	265	-0.09	1.45	3.0	15.5	26.0	15.8	24.9	12.5	2.3
9. Leads to increased regulatory scrutiny	266	1.33	1.39	0.4	5.3	5.6	10.5	28.9	26.7	22.6
10. Leads to patient addiction	265	0.22	1.62	4.5	16.2	11.7	16.6	28.7	16.2	6.0

[a] Bipolar Scale: Extremely Unlikely= -3; Quite unlikely= -2; Somewhat Unlikely= -1; Neither= 0; Somewhat Likely= +1; Quite Likely= +2; Extremely Likely= +3
[b] Number of respondents for each item ranged from 263 to 266; Number of valid respondents used to compute the composite score N= 259

Table 5.17 Outcome evaluations of physicians toward prescribing CR opioids to patients with chronic non-malignant pain

Respondents were asked to rate the following indirect attitude question based on 10 outcome evaluation items:

Question: "How good or bad do you feel each of the following outcomes (if they occurred) would be if you prescribed long-acting opioids to patients with moderate to severe CNMP?"

				Frequency Distribution of Responses (%)[a]						
Outcome Evaluation Items (e_i)	**N[b]**	**Mean**	**SD**	**Extremely Bad (-3)**	**(-2)**	**(-1)**	**Neutral (0)**	**(+1)**	**(+2)**	**Extremely Good (+3)**
1. Leads to abusive behaviors	260	-2.02	1.06	37.3	40.0	14.2	6.2	1.2	0.4	0.8
2. Require additional patient history	260	0.16	1.12	0.4	4.6	18.8	48.1	13.8	11.2	3.1
3. Lengthen patient office visits	260	-0.54	0.98	0.8	12.7	40.8	35.4	7.7	1.2	1.5
4. Effective in controlling pain	260	1.75	1.14	0.8	1.2	2.7	6.9	20.8	41.9	25.8
5. Improve patient quality-of-life	261	2.03	1.13	0.8	1.1	2.3	4.2	13.0	39.1	39.5
6. Less expensive than short-acting opioids	260	1.31	1.16	0.4	0.8	4.6	20.0	24.2	36.2	13.8
7. More difficult to manage patients on multiple Rxs	260	-0.79	0.99	2.7	17.7	46.2	26.2	3.8	3.5	0.0
8. More difficult to manage patients with co-morbidities	259	-0.86	0.98	3.9	17.8	47.9	23.9	3.9	2.7	0.0
9. Leads to increased regulatory scrutiny	261	-1.66	1.30	32.2	26.8	26.1	8.8	3.1	1.9	1.1
10. Leads to patient addiction	258	-1.90	1.13	34.9	34.9	20.2	7.8	0.8	0.4	1.2

[a] Bipolar Scale: Extremely Unlikely= -3; Quite unlikely= -2; Somewhat Unlikely= -1; Neither= 0; Somewhat Likely= +1; Quite Likely= +2; Extremely Likely= +3
[b] Number of respondents for each item ranged from 259 to 261; Number of valid respondents used to compute the composite score N=250

The composite score for indirect attitude was calculated from the cross-products of the mean behavioral belief (b_{1-10}) and outcome evaluation (e_{1-10}) items. Table 5.18 shows the mean cross-product scores (b_{1-10} x e_{1-10}) for each of the 10 questions and the "sum total" score for the overall belief-based attitude ($\Sigma b_{1-10} \Sigma e_{1-10}$). An examination of the 10 items shows both positive and negative belief scores. Overall, the family physician group showed a slightly favorable attitude (Mean=2.96, SD=17.75, possible range -90 to +90) toward prescribing CR opioids to patients with moderate to severe CNMP.

Positive mean scores were observed for five of the 10 belief-based items (items 1, 2, 4, 5, and 6), indicating that physician respondents held favorable attitudes toward CR opioids for CNMP when considering each of the belief items independently. Results show that physicians had a favorable attitude toward prescribing CR opioids for CNMP when considering its "effectiveness in controlling pain" (Mean=3.07, SD=2.85, possible range -9 to +9). In addition, favorable attitudes were observed among the respondents when they considered how CR opioids might "improve the patients' quality of life" (Mean=3.37, SD=3.32).

Negative mean scores were observed for the remaining five belief-based attitude items (items 3, 7, 8, 9, and 10). Physicians were seen to have unfavorable attitudes toward prescribing CR opioids for CNMP when the issue of it leading to regulatory scrutiny was considered (Mean =-2.02, SD=1.06). Unfavorable attitudes were also observed among the respondents when they considered how prescribing CR opioids to CNMP patients may lengthen patient office visits (Mean=-0.64, SD=2.34) or lead to patient addiction (Mean=-0.51, SD=3.81).

Table 5.18 **Indirect Attitudes Composite Score (behavioral beliefs x outcome evaluations)**

Cross-products were calculated for behavioral belief (b_i) and outcome evaluation (e_i) question-items.

Behavioral-belief question: "How likely do you think the following outcomes will occur if you prescribe long-acting opioids to patients with moderate to severe CNMP?"

Outcome evaluation question: "How good or bad do you feel each of the following outcomes would be if you prescribed long-acting opioids to patients with moderate to severe CNMP?"

		Score Range[a]			
Question Items ($\Sigma\ b_ie_i$)	**N[b]**	**Min**	**Max**	**Mean[c]**	**SD**
1. Leads to abusive behaviors ($\Sigma\ b_1e_1$)	261	-9	9	0.12	3.69
2. Requires additional patient history ($\Sigma\ b_2e_2$)	260	-6	9	0.48	2.60
3. Lengthens patient office visits ($\Sigma\ b_3e_3$)	260	-9	9	-0.64	2.34
4. Effective in controlling pain ($\Sigma\ b_4e_4$)	260	-4	9	3.07	2.85
5. Improve patient quality-of-life ($\Sigma\ b_5e_5$)	260	-6	9	3.37	3.22
6. Less expensive than short-acting opioids ($\Sigma\ b_6e_6$)	260	-9	9	0.56	3.01
7. More difficult to manage patients on multiple Rxs ($\Sigma\ b_7e_7$)	261	-9	6	-0.29	2.09
8. More difficult to manage patients with co-morbidities ($\Sigma\ b_8e_8$)	261	-9	6	-0.37	2.13
9. Leads to increased regulatory scrutiny ($\Sigma\ b_9e_9$)	261	-9	9	-2.71	3.80
10. Leads to patient addiction ($\Sigma\ b_{10}e_{10}$)	258	-9	9	-0.51	3.81
Indirect Attitude Composite Score	**250**	**-54**	**53**	**2.96**[d]	**17.75**

[a] Possible score range for each item -9 to +9; Possible range for sum total -90 to + 90
[b] Number of respondents for each item ranged from 258 to 261; Number of valid respondents used to compute the composite score N=250
[c] The average of cross-products for the behavioral-belief items and outcome evaluation items
[d] Sum total represents the "Composite Score" for the 10 belief-based attitudes (Sum of b_1e_1 through $b_{10}e_{10}$) /10)

Belief-based Subjective Norm

The belief-based subjective norm is comprised of two components, normative beliefs and motivation to comply. For normative beliefs (n_i), physicians were asked to rate the likelihood that seven individuals/groups (i.e. referents) would or would not want them to prescribe CR opioids to patients with moderate to severe CNMP. Table 5.19 illustrates the mean frequency and distribution of the normative beliefs (n_{1-7}) which make up indirect subjective norm.

Next, motivation to comply (m_i) was calculated for each of the normative beliefs. Family physicians were asked to respond to the likelihood that they would comply with the wishes of each of the referents. Table 5.20 illustrates the mean frequency and distribution of the motivation to comply components (m_{1-7}) which make up indirect subjective norm.

Table 5.19 Normative beliefs of physicians' toward prescribing CR opioids to patients with chronic non-malignant pain

Respondents were asked to rate the following indirect subjective norm question based on seven normative-belief items:

Question: "How likely is it that each of the following individuals or groups would think that you should prescribe long-acting opioids to patients with moderate to severe CNMP?"

				Frequency Distribution of Responses (%)[a]						
Normative-Belief Item (n_i)	**N[b]**	**Mean**	**SD**	**Extremely Unlikely (-3)**	**(-2)**	**(-1)**	**Neutral (0)**	**(+1)**	**(+2)**	**Extremely Likely (+3)**
1. Regulatory agencies	265	-0.65	1.54	13.6	18.1	25.3	15.8	17.7	9.1	0.4
2. Other primary care physicians	265	-0.12	1.37	3.4	11.7	30.9	14.3	27.2	11.7	0.8
3. Consumer groups	265	0.35	1.45	3.4	7.9	16.2	22.3	29.1	15.5	5.7
4. Pain specialty groups	264	1.16	1.63	3.0	6.4	10.2	5.7	21.6	32.6	20.5
5. Patients	265	1.62	1.04	0.8	0.4	2.6	6.4	29.8	41.9	18.1
6. Texas Medical Board	265	-0.45	1.58	14.7	9.8	24.5	20.0	19.2	10.6	1.1
7. Other healthcare providers and office staff	265	-0.09	1.36	4.9	9.8	23.0	27.2	23.4	10.2	1.5

[a] Bipolar Scale: Extremely Unlikely= -3; Quite unlikely= -2; Somewhat Unlikely= -1; Neither= 0; Somewhat Unlikely= +1; Quite Likely= +2; Extremely Likely= +3

[b] Number of respondents for each item ranged from 264 to 265; Number of valid respondents used to compute the composite score N=264

Table 5.20 Motivation to comply of physicians' toward prescribing CR opioids to patients with chronic non-malignant pain

Respondents were asked to rate the following indirect subjective norm question based on seven motivation to comply belief items:

Question: "How likely are you to do what the following individuals or groups want you to do when prescribing long-acting opiates to patients with moderate to severe CNMP?"

				Frequency Distribution of Responses (%)[a]						
Motivation to Comply Item (m_i)	**N[b]**	**Mean**	**SD**	**Extremely Unlikely (-3)**	**(-2)**	**(-1)**	**Neutral (0)**	**(+1)**	**(+2)**	**Extremely Likely (+3)**
1. Regulatory agencies	257	1.39	1.42	2.3	3.9	3.5	10.5	23.7	34.6	21.4
2. Other primary care physicians	258	0.44	1.19	2.7	3.9	10.9	29.5	37.2	14.0	1.9
3. Consumer groups	258	-0.26	1.22	6.6	9.7	16.7	41.9	20.5	4.3	0.4
4. Pain specialty groups	258	0.90	1.29	1.6	4.7	5.8	20.2	34.5	25.2	8.1
5. Patients	258	0.55	1.13	1.6	4.3	7.4	31.0	39.1	14.0	2.7
6. Texas Medical Board	257	1.57	1.40	1.9	1.6	3.9	14.8	16.3	30.7	30.7
7. Other healthcare providers and office staff	257	0.07	1.22	3.9	7.8	12.5	39.7	26.5	8.6	1.2

[a] Bipolar Scale: Extremely Unlikely= -3; Quite unlikely= -2; Somewhat Unlikely= -1; Neither= 0; Somewhat Likely= +1; Quite Likely= +2; Extremely Likely= +3

[b] Number of respondents for each item ranged from 257 to 258; Number of valid respondents used to compute the composite score N=255

Table 5.21 shows the mean cross-product scores (n_i x m_i) for each of the seven questions and the composite score for indirect subjective norm ($\Sigma n_{1-7}m_{1-7}$). Overall, family physicians showed a positive subjective norm score (Mean=2.19, SD=11.75, possible range -63 to +63). Interpretation of the results indicates a fairly weak positive social pressure for physicians to prescribe CR opioids to patients with moderate to severe CNMP.

Both positive and negative belief scores were observed among the subjective norm items. Positive mean scores were observed for five of the seven subjective norm items (items 2, 3, 4, 5, and 7). Respondents indicated that “pain specialty groups” were likely to want them to prescribe CR opioids to treat CNMP patients (Mean=1.76, SD=3.04) and physicians indicated that were likely to do what the pain specialists wanted them to do. In addition, physicians indicated that they believed “patients” would exert a positive social pressure for them to prescribe CR opioids (Mean=1.03, SD=2.35).

Negative mean scores were observed for belief items one and six For item-1, physician respondents indicated that “regulatory agencies” were not likely to want them to prescribe CR opioids to treat CNMP patients (mean=-0.83, SD=3.51) and respondents indicated that were likely to do what the “regulatory agencies” wanted them to do.

Table 5.21 Indirect Subjective Norm Composite Score (normative beliefs x motivation to comply)

Cross-products were calculated for the normative belief (n_i) and motivation to comply (m_i) question-items.

Normative belief question: "How likely is it that each of the following individuals or groups would think that you should prescribe long-acting opioids to patients with moderate to severe CNMP?"

Motivation to comply question: "How likely are you to do what the following individuals or groups want you to do when prescribing long-acting opiates to patients with moderate to severe CNMP?"

Question Items ($\Sigma\ n_i m_i$)	**N** [b]	**Score Range** [a] **Min**	**Max**	**Mean** [c]	**SD**
1. Regulatory agencies ($\Sigma\ n_1m_1$)	258	-9	9	-0.83	3.51
2. Other primary care physicians ($\Sigma\ n_2m_2$)	258	-9	9	0.24	2.02
3. Consumer groups ($\Sigma\ n_3m_3$)	259	-9	9	0.07	2.07
4. Pain specialty groups ($\Sigma\ n_4m_4$)	257	-6	9	1.76	3.04
5. Patients ($\Sigma\ n_5m_5$)	259	-9	9	1.03	2.35
6. Texas Medical Board ($\Sigma\ n_6m_6$)	258	-9	9	-0.45	3.82
7. Other healthcare providers and office staff ($\Sigma\ n_7m_7$)	260	-6	9	0.37	1.82
Indirect Subjective Norm Composite Score	**255**	**-30**	**45**	**+ 2.19** [d]	**11.75**

[a] Possible score range for each item -9 to +9; Possible range for sum total -63 to + 63
[b] Number of respondents for each item ranged from 257 to 260; Number of valid respondents used to compute the composite score N=255)
[c] The average of cross-products for the behavioral-belief items and outcome evaluation items
[d] Sum total represents the "Composite Score" for the 7 belief-based subjective norms (Sum of n_1m_1 through n_7m_7) /7)

Belief-based Perceived Behavioral Control (PBC)

Indirect perceived behavioral control is comprised of two components, control beliefs and perceived power. For control beliefs (c_i), family physicians were asked to evaluate 10 factors that would make it easier or more difficult for them to prescribe CR opioids to patients with moderate to severe CNMP. Table 5.22 illustrates the mean frequency and distribution of the control beliefs ($c_{1\text{-}10}$) which make-up indirect PBC.

Next, perceived power (p_i) was calculated. Family physicians were asked to rate "how much power" they feel they have over the respective control belief item when prescribing CR opioids to patients with moderate to severe CNMP. Table 5.23 illustrates the mean frequency and distribution for the 10 perceived power items ($p_{1\text{-}10}$).

Table 5.22 Control beliefs of physicians' toward prescribing CR opioids to patients with chronic non-malignant pain

Respondents were asked to rate the following indirect PBC question based on 10 control-belief items:

Question: "Will the following factors make it easy or difficult for you to prescribe long-acting opioids to patients with moderate to severe CNMP?"

				Frequency Distribution of Responses (%)[a]						
Control Belief Items (c_i)	**N[b]**	**Mean**	**SD**	**Extremely Difficult (-3)**	**(-2)**	**(-1)**	**Neutral (0)**	**(+1)**	**(+2)**	**Extremely Easy (+3)**
1. More knowledge in pain management	264	1.34	1.00	0.4	1.5	1.5	12.1	38.3	37.5	8.7
2. Access to pain management tools	264	1.27	1.05	0.4	2.3	1.5	14.8	36.4	36.4	8.3
3. Writing triplicate prescriptions	264	-0.51	1.33	3.8	15.9	40.5	20.1	9.5	7.6	2.7
4. Managing patients who are on multiple medications	264	-0.59	1.12	3.8	11.0	46.2	24.6	9.5	3.8	1.1
5. Receiving full compensation for services associated with prescribing CR opioids	264	0.54	1.46	3.0	6.8	12.5	23.1	26.9	20.5	7.2
6. Access to multidisciplinary teams	264	0.91	1.44	3.0	3.8	11.4	12.5	29.5	30.3	9.5
7. Ready access to patient medical records	264	1.14	1.36	1.5	3.4	8.7	12.1	27.7	33.7	12.9
8. More evidence-based studies	263	1.17	1.26	0.8	2.3	5.7	19.0	28.5	29.7	14.1
9. Managing patients who have co-morbidities	263	-0.29	1.20	2.3	9.1	37.3	28.5	14.4	6.5	1.9
10. Less regulatory scrutiny	263	0.97	1.33	2.7	1.9	6.1	21.3	33.1	23.2	11.8

[a] Bipolar Scale: Extremely Unlikely= -3; Quite unlikely= -2; Somewhat Unlikely= -1; Neither= 0; Somewhat Likely= +1; Quite Likely= +2; Extremely Likely= +3

[b] Number of respondents for each item ranged from 263 to 264; Number of valid respondents used to compute the composite score N=261)

Table 5.23 **Perceived power of physicians' over prescribing CR opioids to patients with chronic non-malignant pain**

Respondents were asked to rate the following indirect PBC question based on 10 perceived power items:

Question: "How much control do you feel you have over the following when it comes to prescribing long-acting opioids to patients with moderate to severe CNMP?"

				Frequency Distribution of Responses (%)[a]						
Perceived Power Items (p_i)	**N[b]**	**Mean**	**SD**	**No Control (+1)**	**(+2)**	**(+3)**	**(+4)**	**(+5)**	**(+6)**	**Complete Control (+7)**
1. More knowledge in pain management	261	4.11	1.12	1.1	0.4	4.2	24.1	28.0	35.2	6.9
2. Access to pain management tools	261	3.41	1.19	2.3	1.5	15.3	36.8	24.1	17.6	2.3
3. Writing triplicate prescriptions	259	3.32	2.07	19.7	2.3	10.8	12.0	18.5	21.6	15.1
4. Managing patients who are on multiple medications	257	3.62	1.21	1.6	3.1	9.3	32.3	29.2	20.2	4.3
5. Receiving full compensation for services associated with prescribing CR opioids	258	1.46	1.48	39.1	14.3	22.1	14.3	6.2	3.5	0.4
6. Access to multidisciplinary teams	259	2.10	1.39	16.6	15.8	28.6	23.6	11.6	3.1	0.8
7. Ready access to patient medical records	259	2.95	1.53	6.9	10.0	20.5	29.0	15.8	13.1	4.6
8. More evidence-based studies	257	2.54	1.57	13.6	12.8	19.5	27.6	15.2	8.9	2.3
9. Managing patients who have co-morbidities	259	3.27	1.32	3.9	5.8	14.3	32.0	26.3	15.4	2.3
10. Less regulatory scrutiny	256	1.09	1.49	56.3	12.5	10.9	10.5	6.3	3.5	0.0

[a] Unipolar Scale: No Control = +1; +2; +3; +4; +5; +6 Complete Control = +7
[b] Number of respondents for each item ranged from 257 to 261; Number of valid respondents used to compute the composite score N=261)

The composite score for indirect perceived behavioral control was calculated from the cross-products of the mean control belief ($c_{1\text{-}10}$) and outcome evaluation ($p_{1\text{-}10}$) items. Table 5.24 illustrates the mean cross-product scores (c_i x p_i) for each of the 10 perceived behavioral control (PBC) items and the "sum total" ($\Sigma\, c_{1\text{-}10}p_{1\text{-}10}$), yielding the indirect PBC composite score. Overall, respondents showed a slightly favorable belief-based PBC composite score (Mean=18.02, SD=32.27, possible range -210 to +210). Interpretation of the indirect PBC score indicates that, overall, respondents felt slightly in control of prescribing CR opioids to patients with moderate to severe CNMP.

Positive mean scores were observed for seven of the 10 PBC items (items 1, 2, 5, 6, 7, 8, and 10). Each of these factor-items were perceived to make it easier for physicians to prescribe CR opioids for CNMP (i.e. physicians felt more in control of prescribing CR opioids when the factor was present). Results showed that possessing "more knowledge in pain management" allowed respondents to feel more in control of prescribing CR opioids for CNMP (Mean=5.62, SD=4.57, possible range -21 to +21). In addition, respondents believed that "access to pain management tools" allowed them to feel more in control over prescribing CR opioids (Mean=4.38, SD=4.23, range -21 to +21). Other items such as access to patient medical records, more evidence-based studies, and access to multidisciplinary teams allowed respondents to feel more in control of prescribing CR opioids for CNMP.

Negative mean scores were observed for three items (items 3, 4, and 9). Each factor-item was perceived to make it slightly more difficult for physicians to prescribe CR opioids for CNMP, meaning physicians felt they had less control over prescribing CR opioids when this factor was present. Results showed that "managing patients on multiple medications" caused respondents to slightly feel in less control of prescribing CR opioids for CNMP (Mean =-1.62 , SD=4.34, possible range -21 to +21). The next sections will examine the results for the hypotheses tests conducted.

Table 5.24 Indirect Perceived Behavioral Control Composite Score (control beliefs x perceived power)

Cross-products were calculated for the control belief (c_i) and perceived power (p_i) question-items.

Control-belief question: "Will the following factors make it easy or difficult for you to prescribe long-acting opioids to patients with moderate to severe CNMP"

Perceived power question: "How much control do you feel you have over the following when it comes to prescribing long-acting opioids to patients with moderate to severe CNMP?"

Question Items ($\Sigma\, c_i p_i$)	N [b]	Score Range [a] Min	Max	Mean [c]	SD
1. More knowledge in pain management ($\Sigma\, c_1p_1$)	262	-12	18	5.63	4.57
2. Access to pain management tools ($\Sigma\, c_2p_2$)	262	-12	18	4.38	4.23
3. Writing triplicate prescriptions ($\Sigma\, c_3p_3$)	259	-18	18	-0.55	5.71
4. Managing patients who are on multiple medications ($\Sigma\, c_4p_4$)	258	-15	18	-1.62	4.34
5. Full compensation for services associated w/ Rx CR opioids ($\Sigma\, c_5p_5$)	260	-8	15	0.73	2.66
6. Access to multidisciplinary teams ($\Sigma\, c_6p_6$)	260	-15	15	2.05	3.66
7. Ready access to patient medical records ($\Sigma\, c_7p_7$)	260	-8	18	3.72	4.41
8. More evidence-based studies ($\Sigma\, c_8p_8$)	257	-15	18	3.10	4.20
9. Managing patients who have co-morbidities ($\Sigma\, c_9p_9$)	260	-10	18	-0.34	4.32
10. Less regulatory scrutiny ($\Sigma\, c_{10}p_{10}$)	259	-15	15	0.92	2.92
Indirect Perceived Behavioral Control Composite Score	**248**	**-75**	**+144**	**+18.02** [d]	**32.27**

[a] Possible score range for each item -21 to +21; Possible range for sum total -210 to + 210
[b] Number of respondents for each item ranged from 257 to 262; Number of valid respondents used to compute the composite score N=248)
[c] The average of cross-products for the behavioral-belief items and outcome evaluation items
[d] Sum total represents the "Composite Score" for the 10 belief-based perceived behavioral control (Sum of c_1p_1 through $c_{10}p_{10}$) /10)

Table 5.25 illustrates a summary of the composite mean scores yielded for each of the direct and indirect TPB constructs.

Table 5.25 Summary of the Composite Scores for the Direct and Indirect Constructs Theory of Planned Behavior Constructs

Variables	N	Score Range Min	Score Range Max	Mean	SD	Possible Score Range	
Direct TPB Constructs							
Willingness	267	-3	+3	0.47 [a]	1.71	-3	+3
Direct Attitude	263	-15	+15	3.96 [b]	6.33	-15	+15
Direct Subjective Norm	264	-3	+3	1.03 [c]	1.52	-3	+3
Direct Perceived Behavioral Control	259	-6	+6	1.45 [d]	3.12	-6	+6
Indirect (belief-based)TPB Constructs							
Belief-Based Attitude	250	-54	+53	2.96 [e]	17.75	-90	+90
Belief-Based Subjective Norm	255	-30	+45	2.19 [f]	11.75	-63	+63
Belief-Based Perceived Behavioral Control	248	-75	+144	18.02 [g]	32.27	-210	+210

[a] Score for 1 willingness measure item
[b] Sum Score for 5 direct attitude items
[c] Score for 1 direct subjective norm item
[d] Sum Score for 2 direct perceived behavioral control items
[e] Composite Score for the 10 belief-based attitudes (Sum of b_1e_1 through $b_{10}e_{10}$) /10)
[f] Composite Score for the 7 belief-based subjective norms (Sum of n_1m_1 through n_7m_7) /7)
[g] Composite Score for the 10 belief-based perceived behavioral control (Sum of c_1p_1 through $c_{10}p_{10}$) /10)

Hypotheses Tests

Several statistical tests were conducted to assess the utility of the Theory of Planned Behavior (TPB) model in explaining family physicians' willingness to prescribe CR opioids to patients with moderate to severe CNMP. This section presents the results of the hypotheses tests conducted.

H1: Attitude, subjective norm, and perceived behavioral control constructs will explain a significant amount of variance in physicians' willingness to prescribe CR opioids to patients with moderate to severe CNMP.

For **H1**, multiple regression analysis was used to regress the willingness variable on to the direct and indirect TPB constructs (attitude, subjective norm, and perceived behavioral control). As shown in Table 5.26, the direct TPB model accounted for 49 percent of the variance in explaining family physicians willingness to prescribe CR opioids to patients with CNMP. Results show all three direct measure constructs as significant predictor variables, yielding a statistically significant overall model ($F_{3,252}$=81.5, p<0.001). Therefore, **H1** was supported using the direct TPB constructs.

Table 5.26 Multiple regression analysis for direct measure constructs of the Theory of Planned Behavior Constructs

				Unstandardized Coefficients		Standardized Coefficients	
Direct Measure Constructs	**R**	**R^2**	**Adjusted R^2**	**B**	**Standard Error**	**Beta**	**P Values**
	0.70	0.49	0.49				
Attitude				0.12	0.014	0.45	p<0.001
Subjective Norm				0.23	0.060	0.21	p<0.001
Perceived Behavioral Control				0.12	0.027	0.22	p<0.001

Total sample size N=256
Dependent variable = Willingness
Independent variables = Attitude, Subjective Norm, and Perceived Behavioral Control

Table 5.27 Multiple regression analysis for indirect measure (belief-based) constructs of the Theory of Planned Behavior

Indirect Measure Constructs	R	R^2	Adjusted R^2	Unstandardized Coefficients B	Unstandardized Coefficients Standard Error	Standardized Coefficients Beta	P Values
	0.63	0.39	0.38				
Attitude				0.04	0.005	0.41	p<0.001
Subjective Norm				0.03	0.008	0.20	p<0.001
Perceived Behavioral Control				0.01	0.003	0.20	p=0.001

Total sample size N=226
Dependent variable = Willingness
Independent variables = Attitude, Subjective Norm, and Perceived Behavioral Control

Table 5.27 shows the indirect (belief-based) TPB constructs accounted for 39 percent of the variance in explaining willingness to prescribe CR opioids to patients with moderate to severe CNMP. Results showed all three belief-based constructs as significant predictor variables in the model. The overall model was statistically significant ($F_{3,222}$=47.4, p<0.001). Therefore, **H1** was supported using the belief-based constructs (indirect TPB model). The following hypotheses examined the predictive strength of each direct and indirect TPB variables.

H2: Favorable attitudes will be a positive and significant predictor of willingness to prescribe CR opioids to patients with moderate to severe CNMP, controlling for subjective norm and perceived behavioral control.

H3: Social norms supporting the prescribing of CR opioids to patients with moderate to severe CNMP will be a positive and significant predictor of willingness to prescribe, controlling for attitude and perceived behavioral control.

H4: Higher perceptions of behavioral control will be a positive and significant predictor of willingness to prescribe CR opioids to patients with moderate to severe CNMP, controlling for attitude and perceived behavioral control.

For **H2**, **H3**, and **H4**, the beta weights for direct and indirect measures of attitude, subjective norm and perceived behavioral control were examined to determine the positive/negative relationships each variable has with willingness (refer to results in Tables 5.26 and 5.27). For **H2**, regressing willingness on attitude yielded a significant overall model with statistically significant and positive beta weights observed for both direct attitude ($\beta=0.45$, $p<0.001$) and indirect attitude ($\beta=0.41$, $p<0.001$) constructs. For **H3**, statistically significant and positive beta weights were observed for both direct subjective norm ($\beta=0.21$, $p<0.001$) and indirect subjective norm ($\beta=0.20$, $p<0.001$) constructs. Results for **H4** showed statistically significant and positive beta weights for direct perceived behavioral control ($\beta=0.22$, $p<0.001$) and indirect perceived behavioral control ($\beta=0.20$, $p<0.001$) constructs. Therefore, **H2**, **H3**, and **H4** were supported using both direct and indirect belief-based TPB models.

Belief-Based Attitudes vs. Willingness

Each of the TPB constructs were significant predictors of willingness to prescribe. As a result, further analyses of the belief-based constructs were conducted to assess how each construct differed among physicians willing to prescribe CR opioids for CNMP and those unwilling. Since attitudes were seen to be a significant positive predictor of willingness, t-tests were conducted to assess which behavioral beliefs ($\mathbf{b}_i$), outcome evaluations ($\mathbf{e}_i$), and products ($\mathbf{b}_i$x$\mathbf{e}_i$) differed significantly among willing and unwilling respondents. For this analysis, willingness was converted to a dichotomous variable. Based on the 7-point bipolar willingness scale, willing respondents scored +1 to +3 and unwilling respondents scored -1 to -3. Neutral responders (scoring 0) were not included in the analysis. Tables 5.28, 5.29, and 5.30 illustrate the differences observed among willing/unwilling physicians for $\mathbf{b}_i$, $\mathbf{e}_i$, and $\mathbf{b}_i$x$\mathbf{e}_i$ components.

For behavioral beliefs, statistically significant differences existed in the mean $\mathbf{b}_i$ scores among physicians willing to prescribe versus those unwilling except for the following item, "will be less expensive than short-acting opioids" (Table 5.28). For $\mathbf{e}_i$, significant differences existed for all mean $\mathbf{e}_i$ scores except for "abusive behaviors," "increased regulatory scrutiny," and "patient addiction" (Table 5.29). All product mean scores $\mathbf{b}_i$x$\mathbf{e}_i$ were significant between willing and unwilling physicians (Table 5.30).

Table 5.28 Behavioral beliefs among family physicians willing versus unwilling to prescribe CR opioids to patients with moderate to severe CNMP

Question: How likely do you think the following outcomes will occur if you prescribe CR opioids to CNMP patients? **Behavioral Beliefs items**	**Mean Scores for Behavioral Belief items (b_i)[a]** **Means for Willing (SD) (n)**	**Means for Unwilling (SD) (n)**	**t-test (P Value)**
a. Will lead to abusive behaviors (N=253)	-0.54 (1.43) (n=166)	0.69 (1.38) (n=87)	-6.64 (p<0.001)
b. Will require additional patient history (N=251)	1.95 (1.05) (n=165)	1.45 (1.42) (n=86)	2.87 (p<0.005)
c. Will lengthen patient office visits (N=254)	0.83 (1.50) (n=167)	1.25 (1.56) (n=87)	-2.10 (p<0.035)
d. Will be effective in controlling pain (N=254)	1.69 (0.96) (n=167)	0.70 (1.35) (n=87)	6.11 (p<0.001)
e. Will improve patient quality-of-life (N=253)	1.80 (0.96) (n=166)	0.45 (1.27) (n=87)	8.65 (p<0.001)
f. Will be less expensive than short-acting opioids (N=254)	0.29 (1.53) (n=167)	-0.07 (1.29) (n=87)	1.96 (p=0.052)
g. Will be more difficult to manage patients on multiple prescriptions (N=254)	-0.38 (1.47) (n=167)	0.51 (1.40) (n=87)	-4.61 (p<0.001)
h. Will be more difficult to manage patients with co-morbidities (N=253)	-0.45 (1.42) (n=166)	0.52 (1.36) (n=87)	-5.24 (p<0.001)
i. Will lead to increased regulatory scrutiny (N=254)	1.12 (1.40) (n=167)	1.70 (1.34) (n=87)	-3.19 (p=0.002)
j. Will lead to patient addiction (N=253)	-0.31 (1.60) (n=166)	1.11 (1.23) (n=87)	-7.87 (p<0.001)

[a] Bipolar Scale: Extremely Unlikely= -3; Quite Unlikely= -2; Somewhat Unlikely= -1; Neither= 0; Somewhat Likely= +1; Quite Likely= +2; Extremely Likely= +3

Table 5.29 Outcome evaluations among family physicians willing and unwilling to prescribe CR opioids to patients with moderate to severe CNMP

Question: How good or bad do you feel each of the following outcomes would be if you prescribed CR opioids for CNMP?	**Mean Scores for Outcome Evaluation items (e_i)** [a]		
Outcome Evaluation items	**Means for Willing (SD) (n)**	**Means for Unwilling (SD) (n)**	**t-test (P Value)**
a. Will lead to abusive behaviors (N=249)	-1.97 (0.95) (n=164)	-2.14 (1.23) (n=85)	1.127 (p=2.62)
b. Will require additional patient history (N=249)	0.34 (1.14) (n=163)	-0.17 (1.04) (n=86)	3.47 (p<0.001)
c. Will lengthen patient office visits (N=249)	-0.41 (0.97) (n=163)	-0.76 (0.99) (n=86)	2.65 (p<0.01)
d. Will be effective in controlling pain (N=249)	2.02 (0.98) (n=163)	1.31 (1.27) (n=86)	4.49 (p<0.001)
e. Will improve patient quality-of-life (N=249)	2.36 (0.86) (n=164)	1.48 (1.35) (n=86)	5.50 (p<0.001)
f. Will be less expensive than short-acting opioids (N=249)	1.43 (1.15) (n=163)	1.09 (1.14) (n=86)	2.193 (p<0.03)
g. Will be more difficult to manage patients on multiple prescriptions (N=249)	-0.63 (0.95) (n=164)	-1.11 (0.99) (n=85)	3.70 (p<0.001)
h. Will be more difficult to manage patients with co-morbidities (N=248)	-0.72 (0.94) (n=163)	-1.13 (1.01) (n=85)	3.19 (p<0.001)
i. Will lead to increased regulatory scrutiny (N=249)	-1.63 (1.20) (n=164)	-1.70 (1.52) (n=86)	3.62 (p=0.064)
j. Will lead to patient addiction (N=248)	-1.82 (1.02) (n=163)	-2.06 (1.30) (n=85)	1.57 (p<0.118)

[a] Bipolar Scale: Extremely Bad= -3; Quite Bad = -2; Somewhat Bad = -1; Neither= 0; Somewhat Good= +1; Quite Good = +2; Extremely Good = +3

Table 5.30 Indirect attitude products (behavioral beliefs x outcome evaluations) of family physicians willing/unwilling to prescribe CR opioids to patients with moderate to severe CNMP

Cross-products were calculated for behavioral belief (b_i) and outcome evaluation (e_i) question-items. **Indirect Attitude Products (b_i x e_i)**	**Means scores for attitude cross-products (b_i x e_i)[a]** **Means for Willing (SD) (n)**	**Means for Unwilling (SD) (n)**	**t-test (P Value)**
a. Will lead to abusive behaviors (N=250)	0.98 (3.40) (n=164)	-1.41 (3.79 (n=86)	5.07 (p<0.001)
b. Will require additional patient history (N=249)	0.96 (2.77) (n=163)	-0.40 (2.17) (n=86)	4.24 (p<0.001)
c. Will lengthen patient office visits (N=249)	-0.27 (2.21) (n=163)	-1.34 (2.48) (n=86)	3.47 (p=0.001)
d. Will be effective in controlling pain (N=249)	3.90 (2.60) (n=163)	1.72 (2.80) (n=86)	6.12 (p<0.001)
e. Will improve patient quality-of-life (N=249)	4.64 (2.73) (n=163)	1.38 (2.81) (n=86)	8.88 (p<0.001)
f. Will be less expensive than short-acting opioids (N=249)	0.93 (3.27) (n=163)	0.02 (2.42) (n=86)	2.47 (p<0.001)
g. Will be more difficult to manage patients on multiple prescriptions (N=249)	0.09 (1.82) (n=164)	-0.98 (2.49) (n=85)	3.50 (p<0.001)
h. Will be more difficult to manage patients with co-morbidities (N=249)	-0.01 (1.88) (n=163)	-1.01 (2.50) (n=86)	3.27 (p=0.001)
i. Will lead to increased regulatory scrutiny (N=259)	-2.24 (3.53) (n=164)	-3.56 (4.23) (n=86)	2.48 (p=0.014)
j. Will lead to patient addiction (N=247)	0.59 (3.55) (n=162)	-2.40 (3.59) (n=85)	6.27 (p<0.001)

[a] Possible score range for each item -9 to +9; Possible range for sum total -90 to + 90

Belief-Based Subjective Norm vs. Willingness

Subjective norm was seen as a significant positive predictor of willingness for both TPB models. As a result, t-tests were conducted for the belief-based subjective norm components. Respondents' normative beliefs ($\mathbf{n}_i$), motivation to comply ($\mathbf{m}_i$), and cross-products ($\mathbf{n}_i$x$\mathbf{m}_i$) were examined to determine if significant differences existed among physicians willing to prescribe CR opioids versus those unwilling to prescribe. Tables 5.31, 5.32, 5.33 show the results of each of the constructs components.

For normative belief items, statistically significant differences existed in all $\mathbf{n}_i$ mean scores between willing and unwilling respondents except for "consumer groups" and "patients" (Tables 5.31). Mean motivation to comply scores were statistically significant among willing and unwilling respondents for only two $\mathbf{m}_i$ items, "pain specialty groups" and "patients" (Table 5.32). Subjective norm cross product scores were significant among the two groups for all $\mathbf{n}_i$x$\mathbf{m}_i$ items except for "consumer groups" and "other health care providers" (Table 5.33)

Table 5.31 Normative beliefs of family physicians willing/unwilling to prescribe CR opioids to patients with moderate to severe CNMP

Question: How likely do you think each of the following referents would want you to prescribe CR opioids to patients with CNMP?	**Mean scores for Normative Beliefs (n_i)[a]**		
Normative Belief Items	**Means for Willing (SD) (n)**	**Means for Unwilling (SD) (n)**	**t-test (P Value)**
a. Regulatory agencies (N=253)	-0.42 (1.52) (n=167)	-1.12 (1.50) (n=86)	3.48 (p<0.001)
b. Other primary care physicians (N=253)	0.22 (1.33) (n=167)	-0.80 (1.28) (n=86)	5.88 (p<0.001)
c. Consumer groups N=253)	0.41 (1.42) (n=167)	0.21 (1.53) (n=86)	1.05 (p=0.293)
d. Pain specialty groups (N=252)	1.53 (1.41) (n=166)	0.44 (1.79) (n=86)	4.91 (p<0.001)
e. Patients (N=253)	1.69 (1.03) (n=167)	1.52 (0.97) (n=86)	1.28 (p=0.203)
f. Texas Medical Board (N=253)	-0.17 (1.59) (n=167)	-0.91 (1.44) (n=86)	3.61 (p<0.001)
g. Other healthcare providers and office staff (N=253)	0.17 (1.34) (n=167)	-0.57 (1.32) (n=86)	4.17 (p<0.001)

[a] Bipolar Scale: Extremely Unlikely= -3; Quite Unlikely= -2; Somewhat Unlikely= -1; Neither= 0; Somewhat Likely= +1; Quite Likely= +2; Extremely Likely= +3

Table 5.32 Motivation to comply among family physicians willing/unwilling to prescribe CR opioids to patients with moderate to severe CNMP

Question: How likely are you to do what the following referents want when prescribing CR opioids to patients with CNMP? **Motivation to Comply Items**	**Mean Scores for Motivation to Comply (m_i)[a]** **Means for Willing (SD) (n)**	**Means for Unwilling (SD) (n)**	**t-Test (P Value)**
a. Regulatory agencies (N=245)	1.42 (1.37) (n=161)	1.38 (1.50) (n=84)	0.217 (p=0.829)
b. Other primary care physicians (N=246)	0.43 (1.25) (n=161)	0.48 (1.15) (n=85)	-0.292 (p=0.771)
c. Consumer groups N=246)	-0.22 (1.30) (n=161)	-0.35 (1.10) (n=85)	0.820 (p=0.413)
d. Pain specialty groups (N=246)	1.18 (1.31) (n=161)	0.34 (1.15) (n=85	4.98 (p<0.001)
e. Patients (N=246)	0.86 (1.00) (n=161)	-0.01 (1.20) (n=85	6.04 (p<0.001)
f. Texas Medical Board (N=245)	1.58 (1.36) (n=160)	1.64 (1.48) (n=85	-.287 (p=0.774)
g. Other healthcare providers and office staff (N=245)	0.18 (1.22) (n=161)	-0.07 (1.21) (n=84)	1.54 (p=0.126)

[a] Bipolar Scale: Extremely Unlikely= -3; Quite Unlikely= -2; Somewhat Unlikely= -1; Neither= 0; Somewhat Likely= +1; Quite Likely= +2; Extremely Likely= +3

Table 5.33 Indirect subjective norm products (normative beliefs x motivation to comply) of family physicians willing/unwilling to prescribe CR opioids to patients with moderate to severe CNMP

Cross-products were calculated for normative beliefs (n_i) and motivation to comply (m_i) question-items. **Indirect Subjective Norm Products (n_i x m_i)**	**Means Scores for SN cross-products (n_i x m_i)[a]** Means for Willing (SD) (n)	Means for Unwilling (SD) (n)	**t-Test (P Value)**
a. Regulatory agencies (N=246)	-0.36 (3.25) (n=161)	-1.66 (3.91) (n=85)	2.77 (p<0.01)
b. Other primary care physicians (N=246)	0.50 (1.92) (n=161)	-0.25 (2.25) (n=85)	2.72 (p<0.01)
c. Consumer groups (N=247)	0.27 (2.16) (n=161)	-0.24 (1.95) (n=86)	1.83 (p=0.068)
d. Pain specialty groups (N=245)	2.49 (3.18) (n=160)	0.52 (2.37) (n=85)	5.02 (p<0.001)
e. Patients (N=247)	1.60 (2.15) (n=161)	0.03 (2.45) (n=86)	5.20 (p<0.001)
f. Texas Medical Board (N=246)	0.19 (3.56) (n=161)	-1.56 (4.15) (n=85)	3.47 (p=0.001)
g. Other healthcare providers and office staff (N=248)	0.49 (1.62) (n=163)	0.09 (2.17) (n=85)	1.62 (p=0.106)

[a] Possible score range for each item -9 to +9; Possible range for sum total -63 to + 63

Perceived Behavioral Control vs. Willingness

Perceived behavioral control (PBC) was seen as a significant positive predictor of willingness for both TPB models. As a result, t-tests were conducted for the belief-based PBC components. Respondents' control beliefs ($\mathbf{c}_i$), perceived power ($\mathbf{p}_i$), and cross-products ($\mathbf{c}_i$x$\mathbf{p}_i$) were examined to determine if significant differences existed among physicians willing to prescribe CR opioids for moderate to severe CNMP versus those unwilling to prescribe. Tables 5.34, 5.35, 5.36 show the results of each of the constructs components.

For control beliefs, statistically significant differences existed for all mean $\mathbf{c}_i$ item scores among willing and unwilling respondents. Further, larger differences in mean scores were observed among the following items, "More knowledge in pain management" and "Access to pain management tools." For perceived power, statistically significant differences existed in the mean $\mathbf{p}_i$ scores between the two groups for the following five items, "Managing patients who are on multiple medications," "Access to multidisciplinary specialty groups," "Ready access to patient medical records," "Managing patients who have co-morbidities," and "Less regulatory scrutiny." All product mean $\mathbf{c}_i$x$\mathbf{p}_i$ scores were statistically significant between willing and unwilling physicians.

Table 5.34 Control beliefs of family physicians willing/ unwilling to prescribe CR opioids to patients with moderate to severe CNMP

Question: Will the following factors make it <u>easy or difficult for you to prescribe</u> CR opioids to patients with CNMP? **Control Beliefs Items**	**Mean Scores for Control Beliefs (c_i)[a]** Means for Willing (SD) (n)	Means for Unwilling (SD) (n)	**t-Test (P Value)**
a. More knowledge in pain management (N=252)	1.69 (0.77) (n=167)	0.73 (1.08) (n=85)	8.14 (p<0.001)
b. Access to pain management tools (N=252)	1.65 (0.82) (n=167)	0.62 (1.10) (n=85)	7.61 (p<0.001)
c. Writing triplicate prescriptions (N=252)	-0.32 (1.34) (n=167)	-0.92 (1.26) (n=85)	3.43 (p<0.001)
d. Managing patients who are on multiple medications (N=252)	-0.39 (1.11) (n=167)	-1.01 (1.04) (n=85)	4.39 (p<0.001)
e. Receiving full compensation for services associated with prescribing CR opioids (N=252)	0.79 (1.46) (n=167)	0.07 (1.36) (n=85)	3.76 (p<0.001)
f. Access to multidisciplinary specialty teams(N=252)	1.17 (1.40) (n=167)	0.44 (1.42) (n=85)	3.92 (p<0.001)
g. Ready access to patient medical records (N=252)	1.44 (1.30) (n=167)	0.64 (1.29) (n=85)	4.67 (p<0.001)
h. More evidence-based studies (N=251)	1.42 (1.12) (n=166)	0.78 (1.38) (n=85)	3.98 (p<0.001)
i. Managing patients who have co-morbidities (N=251)	-0.05 (1.20) (n=167)	-0.77 (1.07) (n=84)	4.64 (p<0.001)
j. Less regulatory scrutiny (N=251)	1.11 (1.34) (n=166)	0.78 (1.28) (n=85)	1.89 (p<0.001)

[a] Bipolar Scale: Extremely Unlikely= -3; Quite unlikely= -2; Somewhat Unlikely= -1; Neither= 0; Somewhat Likely= +1; Quite Likely= +2; Extremely Likely= +3

Table 5.35 Perceived power of family physicians willing/ unwilling to prescribe CR opioids to patients with moderate to severe CNMP

Question: How much control do you feel you have over the following when prescribing CR opioids to patients with CNMP?	**Mean Scores for Perceived Power (p_i)[a]**		
Perceived Power Item	**Means for Willing (SD) (n)**	**Means for Unwilling (SD) (n)**	**t-Test (P Value)**
a. More knowledge in pain management (N=249)	5.20 (0.99) (n=166)	5.02 (1.28) (n=83)	1.19 (p=0.235)
b. Access to pain management tools (N=249)	4.51 (1.17) (n=166)	4.25 (1.25) (n=83)	1.61 (p=0.108)
c. Writing triplicate prescriptions (N=247)	4.31 (2.13) (n=164)	4.37 (2.02) (n=83)	-0.22 (p=0.825)
d. Managing patients who are on multiple medications (N=245)	4.80 (1.14) (n=164)	4.32 (1.32) (n=81)	2.92 (p<0.01)
e. Receiving full compensation for services associated with prescribing CR opioids (N=246)	2.45 (1.47) (n=165)	2.43 (1.55) (n=82)	0.14 (p<0.891)
f. Access to multidisciplinary teams (N=246)	3.23 (1.31) (n=165)	2.84 (1.53) (n=82)	2.07 (p<0.039)
g. Ready access to patient medical records (N=246)	4.10 (1.48) (n=165)	3.66 (1.63) (n=82)	2.15 (p<0.033)
h. More evidence-based studies (N=246)	3.58 (1.57) (n=164)	3.51 (1.62) (n=82)	0.31 (p<0.755)
i. Managing patients who have co-morbidities (N=246)	4.52 (1.28) (n=165)	3.79 (1.34) (n=82)	4.16 (p<0.001)
j. Less regulatory scrutiny (N=246)	2.21 (1.56) (n=163)	1.79 (1.32) (n=81)	2.23 (p=0.027)

[a] Unipolar Scale: No Control = +1; +2; +3; +4; +5; +6, and Complete Control = +7; Possible score range 1 to 7

Table 5.36 Indirect PBC products (control beliefs x perceived power) of family physicians willing/ unwilling to prescribe CR opioids to patients with moderate to severe CNMP

Indirect Perceived Behavioral Control Products (c_i x p_i)	Mean Scores for PBC cross-products (c_i x p_i)[a] Means for Willing (SD) (n)	Means for Unwilling (SD) (n)	t-Test (P Value)
a. More knowledge in pain management (N=250)	8.84 (4.51) (n=166)	3.76 (5.85) (n=84)	7.59 (p<0.001)
b. Access to pain management tools (N=250)	7.43 (4.36) (n=166)	2.62 (5.25) (n=84)	7.68 (p<0.001)
c. Writing triplicate prescriptions (N=249)	0.19 (6.89) (n=164)	-3.46 (6.62) (n=83)	3.98 (p<0.001)
d. Managing patients who are on multiple medications (N=246)	-1.37 (5.48) (n=165)	-3.98 (4.99) (n=81)	3.61 (p<0.001)
e. Receiving full compensation for services associated with prescribing CR opioids (N=246)	1.85 (3.94) (n=166)	0.14 (3.19) (n=83)	3.67 (p<0.001)
f. Access to multidisciplinary teams(N=248)	3.64 (5.16) (n=165)	1.81 (3.97) (n=83)	2.84 (p<0.01)
g. Ready access to patient medical records (N=248)	6.15 (5.78) (n=165)	2.72 (4.20) (n=83)	5.31 (p<0.001)
h. More evidence-based studies (N=247)	5.04 (4.82) (n=163)	3.12 (5.74) (n=83)	2.76 (p<0.01)
i. Managing patients who have co-morbidities (N=248)	0.19 (5.84) (n=166)	-2.26 (4.27) (n=82)	3.73 (p<0.001)
j. Less regulatory scrutiny (N=247)	2.23 (4.11) (n=164)	1.31 (2.70) (n=83)	2.1 (p<0.05)

[a] Possible score range for each item -21 to +21; Possible range for sum total -210 to + 210

Table 5.37 Results of Hierarchical Regression Analysis for direct measure constructs of the Theory of Planned Behavior

Model Sequence	Variables	R^2	Adjusted R^2	R^2 Change	F Change	Unstandardized Coefficients B	Unstandardized Coefficients Standard Error	Standardized Coefficients Beta	P Values
Model 1[a]									
	Attitude					0.13	0.014	0.49	p<0.001
	Subjective Norm	0.45	0.45	0.45	105.26 [c]	0.32	0.059	0.28	p<0.001
Model 2[b]									
	Attitude					0.12	0.014	0.45	p<0.001
	Subjective Norm					0.23	0.060	0.21	p<0.001
	Perceived Behavioral Control	0.49	0.49	0.04	19.15 [d]	0.12	0.027	0.22	p<0.001

Total sample size N=256
Dependent variable = Willingness
[a] Model: Willingness = Direct Measure Attitude (A) + Direct Measure Subjective Norm (SN)
[b] Model: Willingness = Direct A + Direct SN + Direct Measure Perceived Behavioral Control
[c] d.f.=2,253, p<0.001;
[d] d.f.=1,252, p<0.001

H5: The perceived behavioral control construct will significantly increase the explanatory power of the regression model compared to only using attitude and subjective norm to explain family physicians' willingness to prescribe CR opioids to patients with moderate to severe CNMP.

Hierarchical Regression of the TPB Constructs

For **H5**, hierarchical multiple regression analysis was conducted to determine if the direct measure perceived behavioral control construct accounted for a significant increase in the variance explained beyond direct attitude and subjective norm measures. As shown in Table 5.37, the direct attitude and subjective norm measures (Model 1) accounted for 45.4 percent of the variance in explaining physicians' willingness to prescribe CR opioids to patients with CNMP. The perceived behavioral control variable was entered in a separate, last step (Model 2). Adding perceived behavioral control significantly improved the overall model, accounting for 49.3 percent of the variance in physicians' willingness (R^2 change=0.04, F Change $_{1,252}$=19.15, $p<0.001$). Under Model

2, significant beta weights were observed for direct attitude (β=0.45, p<0.001), subjective norm (β=0.21, p<0.001), and perceived behavioral control constructs (β=0.22, p<0.001). Therefore, **H5** was supported using the direct TPB constructs.

A second hierarchical regression analysis was conducted for the indirect (belief-based) measure constructs. As shown in Table 5.38, the belief-based attitude and subjective norm variables (Model 1) accounted for 35.7 percent of the variance in willingness to prescribe. Adding the belief-based perceived behavioral control variable (Model 2) significantly improved the model, accounting for 39.1 percent of the variance in physicians' willingness (R^2 change=0.03, F Change $_{1,222}$=12.37, p<0.001). Significant beta weights were observed for belief-based attitude (β=0.41, p<0.001), subjective norm (β=0.20, p<0.001), and perceived behavioral control (β=0.20, p<0.001). Therefore, **H5** was supported using the indirect TPB constructs.

Table 5.38 Results of Hierarchical Regression Analysis for indirect measure (belief-based) constructs of the Theory of Planned Behavior

						Unstandardized Coefficients		Standardized Coefficients	
Model Sequence	**Variables**	**R^2**	**Adjusted R^2**	**R^2 Change**	**F Change**	**B**	**Standard Error**	**Beta**	**P Values**
Model 1[a]									
	Attitude					0.04	0.005	0.47	p<0.001
	Subjective Norm	0.36	0.35	0.36	61.88[c]	0.04	0.008	0.24	p<0.001
Model 2[b]									
	Attitude					0.04	0.005	0.41	p<0.001
	Subjective Norm					0.03	0.008	0.20	p<0.001
	Perceived Behavioral Control	0.39	0.38	0.03	12.37[d]	0.01	0.003	0.20	p<0.001

Total sample size N=226
Dependent variable = Willingness
[a] Model: Willingness = Indirect Measure Attitude (A) + Indirect Measure Subjective Norm (SN)
[b] Model: Willingness = Indirect A + Indirect SN + Indirect Measure Perceived Behavioral Control
[c] d.f.=2,223, p<0.001
[d] d.f.=1,222, p<0.001

Table 5.39 Results of Hierarchical Regression Analysis for Recent Past Behavior with Direct Measure Theory of Planned Behavior Constructs

Model Sequence	Variables [b]	R^2	Adjusted R^2	R^2 Change	F Change	Unstandardized Coefficients B	Unstandardized Coefficients Standard Error	Standardized Coefficients Beta	P Values
Model 1[a]									
	Attitude					0.08	0.013	0.32	p<0.001
	Subjective Norm					0.17	0.055	0.16	p=0.002
	Perceived Behavioral Control	0.49	0.49	0.49	80.77 [c]	0.07	0.025	0.13	p=0.007
Model 2[b]									
	Recent Past Behavior	0.59	0.58	0.09	58.22 [d]	0.68	0.089	0.38	p<0.001

Total sample size N=255
Dependent variable = Willingness
[a] Model: Willingness = Direct Measure Attitude (A) + Direct Measure Subjective Norm (SN) + Direct Measure Perceived Behavioral Control (PBC)
[b] Model: Willingness = Direct A + Direct SN + Direct PBC + Direct Recent Past Behavior
[c] d.f.=2,251, p<0.001
[d] d.f.=1,250, p<0.001

H6: The recent past behavior construct will significantly increase the explanatory power of the regression model compared to only using the TPB constructs to explain physicians' willingness to prescribe CR opioids to treat moderate to severe CNMP patients.

Hierarchical Regression of the TPB Constructs and Recent Past Behavior

For **H6**, hierarchical multiple regression analysis was conducted to determine if the recent past behavior variable adds to the prediction of family physicians' willingness to prescribe CR opioids to patients with moderate to severe CNMP (beyond the TPB constructs). Table 5.39 illustrates the results of the regression analysis for direct measure TPB constructs. Results show recent past behavior (Model 2) to significantly improve the overall direct measure TPB model, accounting for 59 percent of the variance in physician willingness (R^2 change=0.09, F Change $_{1,250}$=58.22, p<0.001). Under the model, significant beta weights were observed for direct attitude (β=0.32, p<0.001), subjective norm (β=0.16, p=0.002), perceived behavioral control (β=0.13, p=0.007), and recent past behavior (β=0.38, p<0.001). Therefore, **H6** was supported using direct measure TPB constructs.

A second hierarchical regression analysis was conducted using the indirect TPB measures. Shown in Table 5.40, adding recent past behavior (Model 2) significantly improved the belief-based TPB model, accounting for 57 percent of the variance in willingness (R^2 change=0.18, F Change $_{1,221}$=88.85, p<0.001). Significant beta weights existed for belief-based attitude (β=0.25, p<0.001), subjective norm (β=0.10, p<0.001), perceived behavioral control (β=0.17, p<0.001), and recent past behavior (β=0.48, p<0.001). Therefore, **H6** was supported using indirect measure TPB constructs.

Table 5.40 Results of Hierarchical Regression Analysis for Recent Past Behavior with Indirect (belief-based) Measure Theory of Planned Behavior

Block Sequence	Variables	R^2	Adjusted R^2	R^2 Change	F Change	Unstandardized Coefficients B	Unstandardized Coefficients Standard Error	Standardized Coefficients Beta	P Values
Block 1[a]									
	Attitude					0.02	0.005	0.25	P<0.001
	Subjective Norm					0.02	0.007	0.10	P=0.038
	Perceived Behavioral Control	0.39	0.38	0.39 [c]	47.48	0.01	0.003	0.17	P=0.001
Block 2[b]									
	Recent Past Behavior	0.57	0.56	0.18 [d]	88.85	0.87	0.092	0.48	P<0.001

Total sample size N=255
Dependent variable = Willingness
[a] Model: Willingness = Indirect Measure Attitude (A) + Indirect Measure Subjective Norm (SN) + Indirect Measure Perceived Behavioral Control (PBC)
[b] Model: Willingness = Indirect A + Indirect SN + Indirect PBC + Indirect Recent Past Behavior
[c] d.f.=2,251, p<0.001
[d] d.f.=1,250, p<0.001

H7: Physicians who have received continuing education (CE) in pain management will be more willing to prescribe CR opioids to moderate to severe CNMP patients versus physicians who have not received CE.

H8: Physicians who have received CE in pain management will have more favorable attitudes toward prescribing CR opioids to patients with moderate to severe CNMP versus physicians who have not received CE.

Continuing Education vs. Willingness

For **H7** and **H8**, two-tailed t-tests were conducted to examine the mean score differences for willingness and attitude among physicians who received continuing education (CE) in pain management versus physicians those who did not. For **H7**, differences in willingness mean scores were observed between the two groups (willingness score range: -3 = unwilling to +3 = willing). Results showed physicians who received CE in pain management in the last three years were slightly more willing to prescribe CR opioids to patients with moderate to severe CNMP (N=190, Mean=0.60, SD=1.6) versus physicians who had not received CE (N=72; Mean=0.14, SD=1.72). T-test analysis showed the differences between willing and unwilling physicians to be statistically significant ($t=1.97$, d.f.=260, $p<0.05$), therefore **H7** was supported.

Continuing Medical Education vs. Attitudes

For **H8**, t-tests were conducted for both direct and indirect attitude measures. Results showed statistically significant differences for the direct measure of attitude (possible score range -16 to +16) among physicians who had received CME versus those who had not. Physicians who received CME in pain management in the last three years held more favorable attitudes toward prescribing CR opioids to patients with moderate to severe CNMP (N=189, Mean=4.49, SD=6.40) compared to the attitudes of physicians who had not received CE (N=71; Mean=2.45, SD=5.92). The mean score difference between the two groups was statistically significant ($t=2.33$, d.f.=258, $p=0.02$). Therefore, **H8** was supported using the direct attitude construct. T-tests were also performed using the indirect attitude measure (score range -90 to +90). Results showed physicians receiving CME in the last three years held more favorable attitudes toward prescribing CR opioids for CNMP (N=181, Mean=4.21, SD=17.41) compared to those who had no exposure CME (N=66; Mean=-0.046, SD=18.49). No statistically significant differences were found between the groups (t=1.67, d.f.=245, p=0.096). Therefore, **H8** was not supported using the indirect attitude construct.

H9: Family physicians who practice in suburban areas will have a significantly more favorable attitude toward prescribing CR opioids to patients with moderate to severe CNMP versus family physicians who practice in rural or urban areas.

H10: Family physicians who practice in suburban areas will have significantly more favorable social norms supporting the prescribing CR opioids to patients with moderate to severe CNMP versus family physicians who practice in rural or urban areas.

H11: Family physicians who practice in suburban areas will have a significantly stronger perception of behavioral control in prescribing CR opioids to patients with moderate to severe CNMP versus family physicians who practice in rural or urban areas.

Primary Practice Location vs. TPB Constructs

One-way ANOVAs were conducted to determine if physicians' attitudes, subjective norms, or perceived behavioral control toward prescribing CR opioids to patients with CNMP differed by primary practice location (urban, suburban, and rural). For **H9**, **H10**, and **H11**, one-way ANOVAs results showed no statistically significant difference in the mean scores among urban, suburban, and rural physicians for direct measures of attitude ($F_{2,255}$=0.26, p=0.77), direct subjective norm ($F_{2,256}$=1.07, p=0.34), or direct perceived behavioral control ($F_{2,253}$=0.23, p=0.79). In addition, no significant differences were observed for physician practice location and the belief-based measures of attitude ($F_{2,242}$=1.24, p=0.30), subjective norm ($F_{2,247}$=0.21, p=0.81), or perceived behavioral control ($F_{2,256}$=0.32, p=0.73). As a result, **H9**, **H10**, and **H11** were not supported using the direct or indirect TPB constructs.

H12: There is no difference in attitude toward prescribing CR opioids to moderate to severe CNMP patients between male and female physicians.

H13: There is no difference in subjective norms to prescribe CR opioids to moderate to severe CNMP patients between male and female physicians.

H14: There is no difference in perceived behavioral control over prescribing CR opioids to moderate to severe CNMP patients between male and female physicians.

Gender vs. TPB Constructs

Analyses of **H12**, **H13**, and **H14** utilized two-tailed t-tests to examine the mean score differences for attitudes, subjective norms and perceived behavioral control among male and female respondents. No statistically significant differences existed between male and female physicians and mean scores for direct attitude (t=1.88, d.f.=259, p=0.06), direct subjective norm (t=0.72, d.f.=260, p=0.47), or direct perceived behavioral control (t=1.38, d.f.=256, p=0.17). Therefore **H12**, **H13**, and **H14** were supported using direct TPB measure constructs.

No significant differences were found for the belief-based measures of attitude (t=0.49, d.f.=246, p=0.62) or perceived behavioral control (t=0.31, d.f.=245, p=0.76) and gender. Therefore, **H12** and **H14** were supported using the indirect measures of attitude and perceived behavioral control. Statistically significant differences existed in the mean scores for indirect subjective norms and gender (t=2.98, d.f.=251, p=0.003). Male physicians had higher subjective norms toward prescribing CR opioids to CNMP patients (N=156, Mean=3.66, SD=11.37, score range -63 to +63) compared to female physicians (N=97; Mean=-0.70, SD=11.20, score range -63 to +63). As a result, **H13** was not supported when using the indirect subjective norm measure. Additional analyses were conducted on the components that make up the belief-based subjective norm construct (i.e., normative beliefs, motivation to comply, and cross-products).

Table 5.41 Normative beliefs of male and female family physicians toward prescribing CR opioids to patients with moderate to severe CNMP

Question: How likely do you think each of the following referents would want you to prescribe CR opioids to patients with CNMP? Normative Belief Items	Means Scores for Normative beliefs (n_i)[a] Means for Male (SD) (n)	Means for Female (SD) (n)	t-Test (P Value)
a. Regulatory agencies (N=263)	-0.55 (1.56) (n=165)	-0.80 (1.47) (n=98)	1.284 (p=0.200)
b. Other primary care physicians (N=263)	-0.02 (1.40) (n=165)	-0.23 (1.28) (n=98)	1.249 (p=0.213)
c. Consumer groups (N=263)	0.45 (1.54) (n=165)	0.18 (1.26) (n=98)	1.549 (p=0.123)
d. Pain specialty groups (N=263)	1.40 (1.57) (n=164)	0.76 (1.67) (n=98)	3.121 (p=0.002)
e. Patients (N=263)	1.69 (1.01) (n=165)	1.49 (1.09) (n=98)	1.518 (p=0.130)
f. Texas Medical Board (N=263)	-0.35 (1.59) (n=165)	-0.59 (1.55) (n=98)	1.198 (p=0.232)
g. Other healthcare providers and office staff (N=263)	-0.07 (1.38) (n=165)	-0.08 (1.31) (n=98)	0.052 (p=0.959)

[a] Bipolar Scale: Extremely Unlikely= -3; Quite unlikely= -2; Somewhat Unlikely= -1; Neither= 0; Somewhat Likely= +1; Quite Likely= +2; Extremely Likely= +3

T-tests were conducted on the normative belief ($\mathbf{n}_i$), motivation to comply ($\mathbf{m}_i$), and cross-products ($\mathbf{n}_i$x$\mathbf{m}_i$) components to determine what significant differences existed between male and female physicians (Table 5.41, 5.42, 5.43). Table 5.41 shows mean normative belief scores to be statistically significant for "pain specialty groups" (score range -3 to +3). Interpretation of the $\mathbf{n}_i$ table results indicate male respondents were more likely (Mean=1.40, SD=1.57) to believe that pain specialty groups would want them to prescribe CR opioids for CNMP compared to female physicians (Mean=0.76, SD=1.67).

Table 5.42 Motivation to comply between male and female family physicians toward prescribing CR opioids to patients with moderate to severe CNMP

Question: How likely are you to do what the following referents want when prescribing CR opioids to patients with CNMP?	**Means Scores for SN cross-products (n_i x m_i) [a]**		
Motivation to comply	**Means for Male (SD) (n)**	**Means for Female (SD) (n)**	**t-Test (P Value)**
a. Regulatory agencies (N=263)	1.33 (1.51) (n=157)	1.52 (1.21) (n=98)	-1.05 (p=0.295)
b. Other primary care physicians (N=263)	0.46 (1.18) (n=158)	0.48 (1.16) (n=98)	-0.159 (p=0.874)
c. Consumer groups (N=263)	-0.26 (1.28) (n=158)	-0.24 (1.12) (n=98)	-0.93 (p=0.926)
d. Pain specialty groups (N=263)	0.90 (1.35) (n=158)	0.88 (1.21) (n=98)	0.127 (p=0.899)
e. Patients (N=263)	0.68 (1.02) (n=158)	0.32 (1.26) (n=98)	2.424 (p=0.016)
f. Texas Medical Board (N=263)	1.46 (1.50) (n=158)	1.79 (1.13) (n=97)	-2.00 (p=0.046)
g. Other healthcare providers and office staff (N=263)	-0.04 (1.29) (n=157)	0.32 (1.03) (n=98)	-2.344 (p=0.020)

[a] Bipolar Scale: Extremely Unlikely= -3; Quite unlikely= -2; Somewhat Unlikely= -1; Neither= 0; Somewhat Likely= +1; Quite Likely= +2; Extremely Likely= +3

Table 5.42 shows significant mean score differences for motivation to comply among male and female respondents (score range -3 to +3). Results for this belief-based component ($\mathbf{m}_i$) indicate that male respondents are slightly more likely to comply with wishes of the "patient" versus female physicians. However, female respondents were slightly more likely to comply with the wishes of the "Texas Medical Board" or "other healthcare providers" compared to males.

Table 5.43 Subjective Norm (normative beliefs x motivation to comply) between male and female family physicians toward prescribing CR opioids to patients with moderate to severe CNMP

Indirect Subjective Norm Products (n_i x m_i)	Means Scores for SN cross-products (n_i x m_i) [a] Means for Male (SD) (n)	 Means for Female (SD) (n)	t-Test (P Value)
a. Regulatory agencies (N=263)	-0.54 (3.50) (n=158)	-1.37 (3.36) (n=98)	1.87 (p=0.062)
b. Other primary care physicians (N=263)	0.20 (2.08) (n=158)	0.17 (1.69) (n=98)	0.09 (p=0.927)
c. Consumer groups (N=263)	0.24 (2.33) (n=159)	-0.27 (1.50) (n=98)	2.12 (p=0.035)
d. Pain specialty groups (N=263)	2.21 (3.13) (n=157)	1.03 (2.77) (n=98)	3.06 (p=0.002)
e. Patients (N=263)	1.23 (2.27) (n=159)	0.66 (2.41) (n=98)	1.90 (p=0.058)
f. Texas Medical Board (N=263)	-0.13 (3.82) (n=159)	-1.08 (3.68) (n=97)	1.96 (p=0.051)
g. Other healthcare providers and office staff (N=263)	0.43 (1.82) (n=160)	0.18 (1.61) (n=98)	1.08 (p=0.281)

[a] Possible score range for each item -9 to +9; Possible range for sum total -63 to + 63

Table 5.43 illustrates the results of cross-products mean scores among male and female respondents (scores range -3 to +3). Statistically significant differences existed in the $\mathbf{n}_i \mathrm{x} \mathbf{m}_i$ mean scores between male and female respondents. Results indicate that male physicians were more likely to be positively influenced to prescribe CR opioids for CNMP by “consumer groups” and “pain specialty groups” compared to female physicians.

H15: There is no difference in attitude to prescribe CR opioids to moderate to severe CNMP patients and years of experience.

H16: There is no difference in subjective norm to prescribe CR opioids to moderate to severe CNMP patients and years of experience.

H17: There is no difference in perceived behavioral control to prescribe CR opioids to moderate to severe CNMP patients and years of experience.

Physicians Years of Experience vs. TPB Constructs

For **H15**, **H16**, and **H17**, Pearson correlation analyses were conducted to determine if attitude, subjective norm, or perceived behavioral control over prescribing CR opioids for patients with CNMP differed by physicians' years of experience. No statistically significant differences were found for the direct subjective norm (R=-0.05, p=0.212) and perceived behavioral control constructs (R=0.04, p=0.252) and years of experience. However, a negative correlation was observed for direct attitude (R=-0.11, p=0.033) and years of experience. As a result, **H15** was not supported and **H16** and **H17** were supported using the direct measures of TPB. No statistically significant differences were observed for indirect attitude (R=-0.019, p=0.386), subjective norm (R=0.08, p=0.108), or perceived behavioral control (R=-0.07, p=0.130). Therefore, **H15**, **H16**, and **H17** were supported using the indirect TPB constructs.

H18: There is no difference in attitude toward prescribing CR opioids to moderate to severe CNMP patients and physician ethnicity.

H19: There is no difference in subjective norm to prescribe CR opioids to moderate to severe CNMP patients and physician ethnicity.

H20: There is no difference in perceived behavioral control over prescribing CR opioids to moderate to severe CNMP patients and physician ethnicity.

Physicians Ethnicity vs. TPB Constructs

For **H18**, **H19**, and **H20**, one-way ANOVAs were conducted to determine if physicians' attitudes, subjective norms, or perceived behavioral control toward prescribing CR opioids to patients with CNMP differed by ethnicity. As shown in the demographic section 5.7, the ethnic make-up of the sample was Asian or Pacific Islander (N=15), Black/ African American (N=5), Latino/Latin American/ Hispanic (N=31), White/European American (N=194), and other (N=16). For this analysis, due to the low number of African-American respondents, this ethnic group was collapsed into the "other" category. Results of one-way ANOVAs found no statistically significant differences in mean scores for the direct measures of attitude ($F_{3,255}$=1.60, p=0.189), subjective norm ($F_{3,256}$=1.13, p=0.336), and perceived behavioral control ($F_{3,252}$=1.30, p=0.275). Therefore **H18**, **H19**, and **H20** were supported using the direct measures of the TPB construct.

One-way ANOVAs were performed on indirect TPB measures and statistically significant differences existed among the mean scores for belief-based attitude ($F_{3,242}$=2.83, p=0.039) and subjective norm ($F_{3,247}$=2.89, p=0.036) based on ethnicity. However, belief-based perceived behavioral control was not significant ($F_{3,241}$=0.59, p=0.620). As a result, **H18** and **H19** were not supported and **H20** was supported using the indirect measures of TPB.

Post hoc analyses were conducted for the belief-based attitude and subjective norm variables. Tukey HSD showed the mean scores for the belief-based attitude construct (score range -90 to +90) to be significantly higher for White/European Americans (Mean=3.22, SD=17.12) when compared to respondents in the "Other" category (Mean= -8.50, SD=15.89). For belief-based subjective norm (possible scores range from -63 to +63), Tukey HSD showed subjective norm mean scores for Latino/Latin American/ Hispanic respondents (Mean=7.34, SD=13.95) to be significantly higher than Asian/Pacific Islanders (Mean=-2.79, SD=12.04).

Given the small number of respondents in the non-white categories, a non-white group was created. Further analysis was performed to determine if differences existed for the TPB constructs among "white" and "non-white" respondents. White/ European American respondents (N=194) were compared to all of the other ethnic groups that were placed into the "non-white" category (N=73). T-tests yielded no statistically significant differences for direct attitude (t=0.66, d.f.=257, p=0.508) direct subjective norm (t=-0.07, d.f.=258, p=0.946), or direct perceived behavioral control (t=-0.48, d.f.=254, p=0.625). In addition, no significant differences were seen in the mean scores of indirect attitude (t=1.82, d.f.=244, p=0.070), indirect subjective norm (t=-0.83, d.f.=249, p=0.408) and indirect perceived behavioral control (t=-1.06, d.f.=243, p=0.289) among the two groups.

H21: There is no difference in attitude toward prescribing CR opioids to moderate to severe CNMP patients and type of practice.

H22: There is no difference in subjective norm to prescribe CR opioids to moderate to severe CNMP patients and type of practice.

H23: There is no difference in perceived behavioral control over prescribing CR opioids to moderate to severe CNMP patients and type of practice.

Physician Practice Type vs. TPB Constructs

For **H21**, **H22**, and **H23**, one-way ANOVAs were conducted to determine if physicians' attitudes, subjective norms, or perceived behavioral control toward prescribing CR opioids to patients with CNMP differed by the type of physician practice (i.e., solo practice, partnership, group, managed care, hospital, or other). Results from one-way ANOVAs found no significant mean score differences among the different practice types and the direct measures of attitude ($F_{2,253}$=0.80, p=0.550), subjective norm ($F_{2,253}$=1.10, p=0.362), and perceived behavioral control ($F_{2,249}$=0.07, p=0.997). Additionally, no significant mean differences were found for the belief-based measures of attitude ($F_{2,239}$=0.70, p=0.625), subjective norm ($F_{2,245}$=0.74, p=0597), and perceived behavioral control ($F_{2,238}$=0.39, p=0.857). Therefore, **H21**, **H22**, and **H23** were supported using the direct and indirect TPB measures.

5.10 Assumptions of Linear Regression

As discussed in section 4.3, routine pre-analysis screening procedures were conducted to assess the normality of multivariate data. For this study, it was assumed that the following criteria for linear regression analyses: normality, linearity, homoscedasticity and multicollinearity were satisfied. In order to determine if the assumptions for linear regression were violated, an examination of the residuals (predicted minus expected values) was conducted for the four assumptions.

It is assumed in linear regression that residuals are normally distributed for sample data. Normally distributed residuals indicate that sample data used for analysis are drawn from an independent and random sampled population in which the relationship between the dependent (DV) and independent variable (IV) is linear (Tabachnick& Fidell, 2001). Histograms, as well as, normal probability plots were used to inspect the distribution of the residual values. Appendix F includes histograms illustrating residual distributions that appear to be fairly normal. Appendix G shows cumulative probability plots (P-P) conducted. Observations of the P-P plot shows standardized residuals falling along the reference line, indicating a normal distribution of the sample data. Therefore, the assumption of normality was not violated.

The assumption of linearity assumes that the relationship between the DV and IVs is linear (Tabachnick& Fidell, 2001). Appendix H illustrates the scatterplots for the variables of interest. Visual examination of the partial regression plots did not show a curvature in the relationships between the DV and IVs. Further, residuals of both scatterplots reveal a concentration of residuals in the center (“0” value) of the plots at each value of the predicted score. This concentration of residual scores around the center indicates that the assumption for linearity was not violated.

The assumption of homoscedasticity (equal distribution of variances around the regression line) was assessed by examining the scatterplots of standardized residuals against the standardized predicted values. Appendices H and I show the scatterplots used to assess normality and homoscedasticity. Appendix H illustrates residuals for the scatterplot to collect around the center of each plot. Appendix I shows the partial regression scatterplots of residuals of the dependent variable and an independent variable when both variables are regressed separately on the rest of the independent variables. Visual examination of each of the scatterplots shows the residuals to be evenly distributed around the horizontal, indicating the that assumption of homoscedasticity was not violated.

Multicollinearity (and collinearity) involves a linear inter-correlation among variables. It is described as an undesirable occurrence whereby the correlations among the independent variables are highly correlated to one another and become redundant measures of the outcome of interest (Tabachnick& Fidell, 2001). Multicollinearity can cause an over-fitting of the regression model which can make it difficult to determine the particular effects (contributions) of each variable. The ideal regression models consist of predictor variables that correlate highly with the DV but correlate minimally with one another. For this study, multicollinearity was assessed by examining the absolute values of correlation coefficients of the regression variables, variance inflation factors, and eigenvalues (Tables 5.44, 5.45, and 5.46).

Table 5.44 Correlation Matrix for Direct and Indirect Measure Theory of Planned Behavior Constructs, Past Behavior, Continuing Education, and Willingness

TPB Variables		Direct Measures: Willingness	Direct Measures: Attitude	Direct Measures: Subjective Norm	Direct Measures: Perceived Behavioral Control	Direct Measures: Recent Past Behavior	Direct Measures: Continuing Education	Indirect Measures (belief-based): Attitude	Indirect Measures (belief-based): Subjective Norm	Indirect Measures (belief-based): Perceived Behavioral Control	Indirect Measures (belief-based): Recent Past Behavior	Indirect Measures (belief-based): Continuing Education
Direct Measures	Willingness	1.00	0.63	0.52	0.47	0.66	-0.12	0.54	0.36	0.41	0.66	-0.12
	Attitude	0.63	1.00	0.48	0.36	0.50	-0.14	0.61	0.49	0.49	0.50	-0.14
	Subjective Norm	0.52	0.48	1.00	0.44	0.41	-0.08	0.47	0.44	0.31	0.41	-0.08
	Perceived Behavioral Control	0.47	0.36	0.44	1.00	0.43	-0.11	0.42	0.40	0.31	0.43	-0.11
	Recent Past Behavior	0.66	0.50	0.41	0.43	1.00	-0.13	0.43	0.29	0.24	1.00	-0.13
	Continuing Education	-0.12	-0.14	-0.08	-0.11	-0.13	1.00	-0.11	-0.10	-0.02	-0.13	1.00
Indirect Measures (belief-based)	Attitude	0.54	0.61	0.47	0.42	0.43	-0.11	1.00	0.34	0.36	0.43	-0.11
	Subjective Norm	0.36	0.49	0.44	0.40	0.29	-0.10	0.34	1.00	0.31	0.29	-0.10
	Perceived Behavioral Control	0.41	0.49	0.31	0.31	0.24	-0.02	0.36	0.31	1.00	0.24	-0.02
	Recent Past Behavior	0.66	0.50	0.41	0.43	1.00	-0.13	0.43	0.29	0.24	1.00	-0.13
	Continuing Education	-0.12	-0.14	-0.08	-0.11	-0.13	1.00	-0.11	-0.10	-0.02	-0.13	1.00

Table 5.44 illustrates the correlation matrices for the direct TPB measures and the indirect TPB measures. Correlation coefficients > 0.75 are considered to have high-multicollinearity and may be problematic (Graphpad, 1990). For the direct TPB constructs (Ao+SN+PBC), the highest correlation among the IVs was between direct attitude and direct subjective norm (R=0.48). For the indirect TPB constructs, belief-based attitude and perceived behavioral control had the highest correlations (R=0.36). Therefore, multicollinearity was not a serious problem for this model.

Table 5.45 Tolerance and Variance Inflation Factors (VIF) of Independent Variables

Independent Variables	Tolerance	VIF
Direct Measure Attitude	0.649	1.540
Direct Measure Subjective Norm	0.676	1.480
Direct Measure Perceived Behavioral Control	0.734	1.363
Direct Recent Past Behavior	0.665	1.503
Direct Continuing Education	0.977	1.024
Indirect Measure Attitude Belief-Based Attitude	0.720	1.388
Indirect Measure Subjective Norm	0.810	1.234
Indirect Measure Perceived Behavioral Control	0.831	1.203
Indirect Recent Past Behavior	0.759	1.318
Indirect Continuing Education	0.982	1.018

Variance Inflation Factors (VIF) were explored for the direct and indirect TPB models to determine how much of a variable's variance can be explained by the other variables in the model. Table 5.45 illustrates VIF values. VIF values range from 0 to infinity with large VIF values indicating multicollinearity (Noursis, 2005). Unstable regression coefficients have high VIF factor values. Though there is no formal criteria on what constitutes an acceptable VIF value, values > 5 are considered to signify high multicollinearity within a regression model (Tabachnick& Fidell, 2001). The tolerance statistic was examined to determine how much the independent variables are linearly related to one another. The statistic describes the proportion of a variable's variance not accounted for by other IVs in the regression model (Noursis, 2005). The tolerance value has a range of 0 to 1. Variables with low tolerance contribute little information to the model.

Table 5.46 Eigenvalues and Condition Indices

Independent Variables	Eigenvalue	Condition Index
Direct Measure Attitude	0.937	2.081
Direct Measure Subjective Norm	0.507	2.831
Direct Measure Perceived Behavioral Control	0.358	3.367
Direct Recent Past Behavior	0.100	6.361
Direct Continuing Education	0.037	10.503
Indirect Measure Attitude Belief-Based Attitude	1.287	1.644
Indirect Measure Subjective Norm	0.646	2.320
Indirect Measure Perceived Behavioral Control	0.440	2.813
Indirect Recent Past Behavior	0.112	5.567
Indirect Continuing Education	0.036	9.887

Eigenvalues and condition indices were two collinearity diagnostic procedures used to assess correlations among IVs. Eigenvalues provide an indication of the number of distinct dimensions that exist among IVs. Eigenvalues close to zero are considered to be highly intercorrelated and small changes in the data values may lead to large changes in the estimate coefficients (Noursis, 2005). Condition indices were also examined for the two models. Condition index values are calculated from the square root of the ratios of the largest eigenvalue to each successive eigenvalue (Noursis, 2005). A condition index > 15 indicates potential collinearity problem. Table 5.46 shows the eigenvalues and condition indices. Collinearity among the data was not a serious problem for the direct and indirect TPB regression models.

CHAPTER 6: DISCUSSION

This chapter discusses the findings of this research study. The chapter is divided into four sections: The first section includes a brief discussion of the focus group research used to develop the instrument. Next, the second section discusses significant and important findings, generated from the data analyses. The third section discusses the limitations of the study. Finally, the fourth section includes direction for future research and the conclusion.

The purpose of this research study was to better understand factors that explain family physicians' (FPs) willingness to prescribe controlled-release opioids (CR opioids) to patients with moderate to severe chronic non-malignant pain (CNMP). The goals of the study were to: (1) determine if the Theory of Planned Behavior (TPB) was a useful model in explaining physicians' willingness to prescribe CR opioids, (2) determine if the TPB constructs (i.e., attitude, subjective norm, and perceived behavioral control) as well as recent past behavior (RPB), and (3) determine if differences in attitude, subjective norm, perceived behavioral control, and RPB existed among willing and unwilling physicians based on demographic and practice characteristics.

6.1 Focus Group Findings

The focus group sessions generated the qualitative data that were used to develop the study's questionnaire instrument. Open-ended elicitation interviews with 15 family physicians identified salient beliefs concerning positive and negative consequences of prescribing CR opioids to patients with moderate to severe CNMP. Results of the focus group interviews confirmed much of what has been published in the literature regarding physicians' views towards opioids and CNMP (Turk *et al.*, 1994; Potter *et al.*, 2001; Morley-Forster *et al.*, 2003).

Willingness. As a general inquiry, physicians were asked to describe what comes to mind when prescribing CR opioids. Initial responses included abuse, diversion, addiction, withdrawal, and drug seeking. Interestingly, the concept of effective pain control was not initially discussed. Maybe physicians did not immediately address this point because it was understood that this class of analgesic provides the highest level of pain relief. Next, focus group participants were asked how willing they were to prescribe CR opioids for CNMP. Generally speaking, most of the physicians interviewed indicated that they were willing to prescribe CR opioids to treat their CNMP patients. However, several physicians indicated strong reservations about using CR opioids as the only method of pain control. For example, one physician indicated that he was more unlikely to prescribe CR opioids due to concerns that his patients would exhibit malingerer type behaviors or become complacent with their standard of care once placed on chronic opiate therapy. Other physicians who agreed further emphasized the need for a holistic or comprehensive pain management approach to treating CNMP patients (e.g., physical therapy, counseling, and other non-opioid treatment methods). As a follow-up, focus groups members were asked how likely they were to prescribe CR opioids. All of the focus group participants indicated that they were generally willing to prescribe CR opioids to those patients who needed it.

Attitudes. Physicians were asked to describe the advantages and disadvantages of prescribing CR opioids to patients with moderate to severe CNMP. A majority of physicians interviewed believed that prescribing CR opioids could lead to abusive drug behaviors. Most physicians also indicated that a thorough patient history would be required if CR opioids were prescribed. Positive normative beliefs identified included the effectiveness of CR opioids in controlling pain, the effects they have on patient quality-of-life, and cost savings compared to short-acting alternatives. Interestingly, physicians discussed the association of placing patients on CR opioid therapy and the amount of time it consumes during their office visits. Several physicians indicated that it was not uncommon to have office visits lasting one to two hours when chronic pain patients who were placed on opioids. Further, focus group discussions found that treating CNMP patients becomes mentally exhausting for physicians due to the level of probing required by physicians to learn the full extent of their patients' pain. The respondents felt that additional counseling time was required to create and monitor CNMP treatments using more potent opiate analgesics such as CR opioids. Other salient beliefs identified included the effects of CR opioids when managing patients on multiple medications and/or co-morbidities, the potential of patient addiction, and concerns of regulatory scrutiny. A total of 10 normative belief items were used in the web questionnaire.

Social norms. Physicians were asked to list individuals or groups who would or would not approve of family physicians prescribing CR opioids to patients with moderate to severe CNMP. A total of 15 referents were identified from the physician elicitation interviews. The most frequent normative belief elicited by participants included the effects of regulatory agencies on physician opioid prescribing behaviors. Participants generally believed that regulatory agencies would only approve of limited prescribing of CR opioids for CNMP. Focus group findings were consistent with the literature whereby other salient referents identified by the focus group included colleagues, pain specialists, other health providers, patients, and consumer groups (Turk *et al.*, 1994; Potter *et al.*, 2001; Morley-Forster *et al.*, 2003). Several physicians indicated the need to establish a closer working relationship with pain specialists when deciding how to treat their moderate to severe chronic pain patients. However, it appeared that an equal number of physicians voiced concerns regarding pain specialty providers. Specifically, several family physicians felt that many of their patients who were referred to a pain specialist received the "usual standard of care" which often resulted in expensive and short-term pain relief therapy. Participants indicated that it was normal for patients with severe chronic back pain who are referred to a pain specialist to return back to the family physician for follow-up care once the specialist determined that long-term therapies are required to manage the patients' pain. Of the referents identified, a total of seven salient normative belief items were used in the web questionnaire.

Perceived behavioral control. Physicians were asked to list factors that they believed would make it easier or more difficult to prescribe CR opioids to patients with moderate to severe CNMP. Of the more frequent beliefs mentioned, a majority of participants felt that having more knowledge in pain management would make it easier for them to prescribe CR opioids. Physicians also indicated that access to more evidence-based studies and pain management tools (e.g., algorithms, protocols, guides, contracts, diagnostic kits) would make it easier to prescribe. Having to write triplicates made it more difficult for participants to prescribe CR opioids for CNMP. Other salient beliefs that participants perceived would make it easier/difficult to prescribe CR opioids included receiving complete compensation for services associated with prescribing CR opioids, having access to multi-disciplinary teams, prescribing to patients with co-morbidities or on multiple medications, and risk of regulatory scrutiny. A total of 10 control belief items were used in the web questionnaire.

Overall, focus group participants appeared to hold strong beliefs regarding the use of long-acting opiates in CNMP. Beliefs that took up a majority of the discussion were those concerning patient abuse and diversion. In general, focus group participants indicated that they did not have much concern regarding investigation by regulatory agencies. However, when the discussion turned to managing a high volume of chronic pain patients specifically in their own practice, several physicians expressed the need for caution in prescribing too many opiates due to the potential of raising flags that could result in the subsequent investigation by the of Drug Enforcement Agency (DEA) or Texas Medical Board. Physicians also raised concerns about the difficulty of establishing and maintaining a trusting relationship with new patients who presented with signs of chronic pain. They also pointed to concerns of turning their patients into potential abusers, which complicated their decisions to prescribe CR opiates for CNMP. The focus group discussed the stigma attached to "over prescribing" opiate analgesics to their patients. The avoidance of appearing as a "dope pusher" in the community and among their colleagues sometimes affected their prescribing decisions. Further, they did not want to be targeted by drug seeking patients.

Physicians criticized the length and repetitive nature of the elicitation interviews. Specifically, physicians were challenging the way that questions were being asked. They were also resistant to the term controlled-release opioids being used to describe long-acting opiates and often requested clarification of the type and duration of chronic non-malignant pain that was being discussed. Overall, the discussions held among focus groups participants provided invaluable insight into some of the underlying issues to prescribing CR opioids.

6.2 Summary of Study Findings

As hypothesized, the key determinants of family physicians' willingness to prescribe CR opioids to patients with moderate to severe CNMP included the attitude, subjective norm, and perceived behavioral control. Study findings showed each of the constructs played a significant role in explaining physicians' overall willingness to prescribe. In addition, family physicians' past prescribing behavior served as a relatively strong predictor of their future intentions (i.e., willingness) to prescribe.

Willingness

In this study, the majority of family physicians (63%) surveyed were willing to prescribe CR opioids to patients with moderate to severe CNMP. However, one-third of physicians indicated that they were unwilling to prescribe long-acting opioids for this condition. This figure seems high in light of the growing acceptance of CR opioids to treat CNMP (Arkinstall *et al.*, 1995; Davis *et al.*, 2003; Goli& Finley, 2005). Findings from this study are comparable to data from a 1997 California survey and a 2001 Canadian study which both reported that 35 percent of primary care physicians (PCPs) were not willing to prescribe long-acting opioids to patients with CNMP, even after exhaustive attempts using other treatments. (Potter *et al.*, 2001; Morley-Forster *et al.*, 2003). The rationale for physicians' willingness can be attributed to the perceptions of risks and benefits they associate with the use of CR opioids among patients with CNMP. The literature points to a variety of factors that are involved in influencing physicians' willingness to prescribe, especially when long-acting opioids are considered (Turk *et al.*, 1994; Potter *et al.*, 2001; Morley-Forster *et al.*, 2003). Using the TPB model, this study examined some of the predictors of willingness (i.e., attitudes, subjective norm, perceived behavioral control, and recent past behavior) to determine how these factors may potentially influence physicians' prescribing behavior.

Attitude

For this study, Texas family physicians held a slightly favorable (if not fairly neutral) attitude toward prescribing CR opioids to patients with moderate to severe

CNMP. As seen in previous studies, attitude was observed to be highly correlated with willingness (i.e., intentions) among physicians (Millstein, 1996; Lambert *et al.*, 1997; Walker *et al.*, 2001). In this study, the majority of family physicians believed that prescribing CR opioids would be beneficial to patients with moderate to severe CNMP. In addition, over three-fourths of the physicians surveyed felt that long-acting opioids were not only effective in controlling chronic pain among CNMP patients but were also likely to improve patients' overall quality of life. However, physicians were almost evenly divided in their beliefs that prescribing CR opioids for CNMP would lead to abusive behaviors among their patients (41% felt it would likely lead to abuse versus 44% who did not). One-third of family physicians believed that prescribing CR opioids for CNMP would lead to patient addiction, despite evidence from previous studies indicating that the risk of patient addiction to prescribed opioids is relatively low (Porter& Jick, 1980; Portenoy, 1994). One explanation for these results could be the clarity of the term addiction. Research has shown that the terms addiction, physical dependence and tolerance are often used interchangeably among physicians. For example, Potter *et al.* (2001) found that physician concerns about these three conditions were highly intercorrelated when considering their willingness to prescribe opioids for CNMP. This raises the issue that physicians may be unclear about what distinguishes one of these outcomes from another which may have skewed the results (since attitudes regarding physical dependence and tolerance were not assessed).

Significant differences in attitudes were found among respondents "willing to prescribe" CR opioids for CNMP versus those "unwilling to prescribe." As expected, Texas family physicians (34%) who were unwilling to prescribe were found to have less favorable attitudes toward prescribing CR opioids compared to willing physicians. Unwilling physicians tended to believe that prescribing CR opioids would lead to patient abuse and addiction, resulting in more negative attitudes toward prescribing it for CNMP. These findings are not surprising and concerns of patient misuse of CR opioids are not without merit (as pointed out in section 2.7.1). Educational efforts should be directed at clarifying the misconceptions of addiction and abuse so that physicians base their prescribing decisions on a more accurate understanding of the disease and less on erroneous preconceptions which could ultimately interfere with effective pain management.

Family physicians' attitudes were seen to differ on several other belief items. Not all physicians believed that long-acting opiates were effective in controlling pain, despite recent studies (Hale *et al.*, 1999; Salzman *et al.*, 1999; Davis *et al.*, 2003) showing CR opioids to be as effective as short-acting opiates in managing CNMP. In addition, physicians unwilling to prescribe CR opioids were less likely to believe that long-acting opiate therapies improved patient quality of life among CNMP sufferers. The groups' beliefs are not without reason. Even though research suggests that CR opioids can significantly improve quality of life, experts agree that more evidence-based data is needed to substantiate the recently discovered attributes of CR opioids, particularly as it relates to improving quality of life (e.g., less sleep disturbances, overall improvement in physical functioning) (Fisher, 2004a). Consequentially, a greater systematic effort is needed to collect and disseminate information from published studies that have demonstrated the actual benefits of CR opioids as they relate to quality of life indicators.

This study found physicians who were unwilling to prescribe were more likely to believe that CR opioids would make it more difficult for them to manage CNMP patients on polypharmacy or with co-morbidities. Clinical findings have shown that most patients who are prescribed CR opioids for CNMP often require more than one drug to achieve adequate pain control, through combinations of non-opioid, opioid, and adjuvant therapies (McCarberg, 2004). The issue of using multiple medications to treat CNMP is further complicated by the limited data on which combinations of non-opioid and opioid therapies work best. Side effects, drug interactions, ease of use and cost must also be considered. It is understandable that when considering these factors, prescribing of CR opioids could further complicate the patient's existing drug regimen, hence discouraging physicians from using this type of opiate therapy. Physicians face similar issues when deciding if a CR opioid is appropriate for CNMP patients with co-morbid conditions (given that they are likely to be on other therapies to manage these conditions). Family physicians should turn to pain specialty groups when requiring guidance in using CR opioid therapies among polypharmacy and co-morbid patients. Further, continuing education curricula should focus on pain management guidelines to assist physicians in deciding what CNMP therapy is appropriate.

Other areas where physician attitudes differed significantly included beliefs that prescribing CR opioids for CNMP would lengthen patient office visits and require a more in-depth collection of patient history. Another important study finding showed that over 78 percent of respondents believed that prescribing CR opioids would likely lead to regulatory investigation. Less favorable attitudes were observed among physicians unwilling (34%) to prescribe CR opioids for CNMP (Mean=-3.56, SD=4.23, range -9 to +9) when the issue of regulatory scrutiny was considered, compared to physicians who were willing to prescribe (62%) (Mean=-2.24, SD=3.53, $p=0.014$). Fear of regulatory scrutiny has often been cited as negatively affecting physician willingness in other studies (Turk, 1996; Turk& Okifuji, 1997; Potter *et al.*, 2001; Morley-Forster *et al.*, 2003; Ponte& Johnson-Tribino, 2005). For example, approximately 40 percent of physicians in the Potter *et al.* (2001) California survey indicated that fear of regulatory investigation restricted their use of opioids for CNMP. The official stance of regulatory bodies in Texas is that they support the appropriate use of stronger-acting opioids for CNMP (Texas Medical Board, 2005). Despite recently published guidelines, physicians are reluctant to prescribe what they may consider excessive amounts of opioids. Further, it is not clear what affect, if any, these guidelines have on increasing or decreasing physician concerns of regulatory scrutiny. Future studies should examine whether differences in family physician attitudes and willingness to prescribe CR opioids are related to the awareness of the guidelines in Texas.

Subjective Norm

As hypothesized, subjective norm was a key determinant of physicians' willingness to prescribe. Like the attitude construct, family physicians held a slightly positive (if not fairly neutral) subjective norm. Most physicians surveyed believed that referents would be supportive in their prescribing of CR opioids for moderate to severe CNMP. Family physicians were more likely to be influenced (i.e., comply with requests) by regulatory agencies (82%), pain specialty groups (68%), other primary physicians

(53%), and (importantly) their patients (56%). A closer look at the study results showed a majority of physicians believed that regulatory agencies (e.g., Texas Medical Board) would not condone their prescribing of long-acting opioids for CNMP. Further, over 80 percent of physicians indicated that they were likely to comply with requests of regulatory agencies when it came to prescribing CR opioids. These findings are not surprising given that established federal/state-based opioid policies have been focused on reducing diversion and prescription drug abuse, particularly for this class of opiate analgesic. For this reason, many physicians are keenly aware of the various regulatory efforts to discourage prescribing of this class of opiates and the tactics used to investigate clinicians identified as having excessive or suspicious opiate prescribing behaviors (Joranson *et al.*, 2002).

Recently, agencies such as the DEA have publicly acknowledged the crucial role CR opioids play in enhancing the quality of care among patients suffering from moderate to severe CNMP (Gallagher, 2004). The agency clarified its new commitment to avoid regulatory restrictions that obstruct the appropriate use of opiate analgesics and improve its policies on supporting the prescribing of long-acting opioids for CNMP. Other agencies such as the Federation of State Medical Boards (FSMB) and the Texas Medical Board have articulated similar doctrines, conveying a need to improve their current policies to promote the legitimate prescribing of long-acting opioids for moderate to severe CNMP (FSMB, 2003; Texas Medical Board, 2005). Despite the recent positive changes in regulatory policies toward CR opioids, it appears many physicians (in this survey) continue to be reluctant to prescribe CR opioids for CNMP because of regulatory scrutiny. As pointed in the attitude section, further study should be conducted to assess family physicians' awareness of Texas regulatory guidelines as they relate to prescribing CR opioids for CNMP. In addition, increased efforts should focus on educating Texas family physicians about current regulatory policies to improve their knowledge and change negative normative beliefs toward CR opioids in pain management. Learning modules outlining current state medical board pain guidelines (e.g., Texas intractable pain treatment act of 1989) would be an appropriate method to educate physicians on prescribing standards for CR opioid and other controlled substances.

Pain specialists were another group that influenced physicians' willingness to prescribe. This study found that 68 percent of respondents were likely to comply with the recommendations of pain specialty groups when considering prescribing CR opioids for CNMP. However, statistically significant differences in the normative belief scores for pain specialists were observed between willing and unwilling physicians. Physicians unwilling to prescribe (Mean=0.44, SD=1.79, , range -3 to +3) were less likely to believe that pain specialists would support their prescribing of CR opioids for CNMP compared to those willing to prescribe (Mean=1.53, SD=1.41, $p<0.001$). Furthermore, respondents unwilling to prescribe CR opioids indicated they were less likely to comply with requests from pain specialists when it came to treating CNMP patients with long-acting opiates. Various hypotheses can be presented as to why unwilling physicians are less inclined to comply with pain specialists requests. One explanation may involve the level of access (i.e., exposure) physicians have to pain specialty groups. Several studies have suggested that physicians who do not have adequate access to pain specialists are less supportive in using long-acting opioids to manage chronic pain (Jamison *et al*., 2002). A California study by Potter *et al*. (2001) examining physicians' attitudes toward CNMP found 45 percent of primary care physicians (PCPs) felt they had inadequate consultation and referral services to assist them in adequately managing their CNMP patients. When asked about their use of pain specialists, 52 percent of physicians reported that they required (always or usually) their patients to undergo evaluation by a pain specialist before prescribing opioids for CNMP. These findings are comparable to a Canadian study that reported 40 percent of physicians felt that pain specialists are not common where they practiced. Based on these findings, pain specialists may not be fully available to assist family physicians. Findings from this and other studies should be used to highlight the importance of community-based pain specialty groups and the need for more information about pain management resources available to family physicians.

Over half of the physicians surveyed (56%) indicated that they were likely to comply with patients who requested long-acting opioids for CNMP. These results are consistent with previous findings on the effects of patient demands on physician prescribing (Stevenson *et al.*, 1999). Examination of responses among willing and unwilling respondents found small but significant differences in the mean scores between the two groups. Willing physicians (Mean=0.86, SD=1.00, $p<0.001$, range -3 to +3) were slightly more likely to comply with requests from patients with CNMP compared to unwilling physicians (Mean=-0.01, SD=1.20). Though CNMP patients can influence physicians' decisions to prescribe CR opioids, physicians are seen to be particularly cautious when deciding to use stronger-acting opioids for chronic conditions (Potter *et al.*, 2001). Results from the Turk *et al.* (1997) study found patients who were observed to have significant functional limitations were more likely to be prescribed opioids. However, verbal reports of pain, distress, and disability were reported to play a mild role among patients who were prescribed opioids from those who did not. It is not clear what effect patient requests have on increasing or decreasing physician's willingness to prescribe, but additional studies should further examine this issue. Another area where subjective norms significantly differed among willing and unwilling respondents was for other primary care physicians. Family physicians who were unwilling to prescribe tended to believe that other primary care physicians would not want them to prescribe CR opioids for CNMP. Though no known studies have specifically examined the influence of colleagues on physician prescribing of CR opioids for CNMP, these findings are comparable to the Weinstein *et al.* (2000b) survey which reported that half of physicians disagreed with the statement that their colleagues were more willing to give narcotics for cancer pain.

Perceived Behavioral Control

Overall, family physicians felt that they were somewhat in control of prescribing CR opioids to CNMP patients (though the overall PBC score was marginally above neutral). The majority of family physicians surveyed (85%) indicated that possessing more knowledge in pain management would improve their level of control over prescribing CR opioids for CNMP. Many of these physicians also indicated that access to pain management tools (81%) and more evidenced-based studies (61%) would make it easier for them to prescribe CR opioids. These findings corroborate previous research that suggest that physicians' knowledge in the use of opioids in chronic pain management is deficient (Marks& Sachar, 1973; Von Roenn *et al.*, 1993; Turk *et al.*, 1994; Von Gunten& Von Roenn, 1994; Turk, 1996; Weinstein *et al.*, 2000a, 2000b; Gilson& Joranson, 2001; Potter *et al.*, 2001). For example, a survey of West Virginian family physicians revealed that respondents had difficulty in understanding how to properly manage opioid-induced adverse events and side effects (Ponte& Johnson-Tribino, 2005). Further, in the Morley-Forster *et al.* (2003) study, 68 percent of physicians felt that CNMP was not well managed within their practices. A primary reason given for this finding involves physicians' beliefs that their formal medical training did not adequately prepare them to effectively manage pain. Regardless, CNMP patients may be suffering due to physician knowledge gaps in pain management. It seems logical to conclude that additional educational programs focused on educating family physicians about current pain management practices (involving up-to-date pain management guidelines, treatment protocols, and standards of practice supported by evidence-based research) would improve their overall clinical knowledge in treating CNMP.

Interestingly, a majority of physicians (71%) indicated that receiving full compensation for services associated with prescribing CR opioids for CNMP positively affected their control beliefs over prescribing CR opioids. This finding may be due, in part, to physician beliefs that pain management is a time consuming practice. Like previous research (Morley-Forster *et al.*, 2003; Ponte& Johnson-Tribino, 2005), physicians in this study, may have felt that additional compensation was needed for the amount of time spent on counseling CNMP patients, particularly when those patients are placed on chronic opioid therapy (refer to focus group section 6.1). Other areas where perceived behavioral control differed significantly included regulatory scrutiny. Almost 70 percent of physicians surveyed believed that less regulatory scrutiny would make it easier for them to prescribe CR opioids. In general, regulatory scrutiny/agencies were seen as a barrier for all three constructs used to assess willingness.

When examining the differences in perceived behavioral control among willing/unwilling physicians, it was found that physicians who were willing to prescribe CR opioids for CNMP felt more in control when managing patients on multiple medications and/or co-morbidities compared to those unwilling. Unwilling physicians felt writing triplicate prescriptions made it more difficult for them to prescribe CR opioids compared to willing physicians. Additional findings showed similar differences in the final mean composite scores for each of the perceived behavioral control items. It is important to note that these findings should be reviewed with some caution due in part to methodologies used to assess the perceived behavioral control construct. For example, there is a lack of consensus in the literature on the most appropriate scaling technique that should be used to assess the indirect PBC measures. Further exploration on the implication of the PBC construct is needed.

Recent Past Behavior

As hypothesized, past prescribing behavior was found to significantly increase the explanatory power of the study model. When recent past behavior was added to the regression model, belief-based TPB accounted for 57 percent of the variance in willingness (R^2 change=0.18, F Change $_{1,221}$=88.85, $p<0.001$). Existing theoretical literature have shown previous behavior to substantially add to the predictability of the TPB model (Millstein, 1996; Walker *et al.*, 2001).

Study findings showed that 17 percent of respondents indicated that they "never" prescribed CR opioids to patients with moderate to severe CNMP. However, these responses substantially differed from data reported in the Potter *et al.* (2001) study, which found that one-third of primary care physicians never used long-acting opioids to treat CNMP patients. Compared to the Potter *et al.* (2001) study, results from this study imply that Texas family physicians may prescribe CR opioids more often to treat CNMP. It is unclear if Texas family physicians actually prescribe long-acting opioids for CNMP more often compared to California PCPs. Regardless, study findings confirmed Ajzen's (1991) premise that past experience with the behavior of interest (i.e., prescribing CR opioids) is considered to provide important information with regard to an individual's future behavior.

Continuing Medical Education

This study examined the relationship between physicians receiving continuing medical education (CME) in pain management and their willingness to prescribe CR opioids for CNMP. As hypothesized, physicians who received CME in pain management over the last three years were somewhat more willing to prescribe CR opioids to their CNMP patients compared to those who did not receive this type of CME. Differences in mean scores between the willing (Mean=0.60, SD=1.6, range -3 to +3) and unwilling physicians (Mean=0.14, SD=1.72) were statistically significant (t=1.97, d.f.=260, $p<0.05$), suggesting a relationship between CME and willingness to prescribe. However, as this was a cross-sectional study, a causal relationship between willingness and CME cannot be established without further study. Future research should include a longitudinal/pretest-posttest study design to examine the effects of continuing education interventions on willingness.

The relationship between family physician attitudes and CME was also examined. Study findings showed that physicians who received CME in pain management in the last three years held more favorable direct attitudes toward prescribing CR opioids for CNMP compared to physicians who did not receive pain management CME. Mean score differences between the willing (Mean=4.49, SD=6.40, range -3 to +3) and unwilling physicians (Mean=2.45, SD=5.92) were statistically significant (t=2.33, d.f.=258, $p=0.02$), however, indirect attitudes were not significantly different. Similar to findings in other studies examining continuing education in pain management and attitudes toward CR opioids (Gilson& Joranson, 2001; Gourlay *et al.*, 2004; McCarberg, 2004; Potter *et al.*, 2004; Otis& Fudin, 2005), it is possible that CME activities can be used to positively reinforce family physician attitudes toward CR opioids in pain management.

Other Variables

Other barriers have been found to affect physicians' pain management practice. As previously discussed, negative beliefs regarding addiction, abuse, regulatory scrutiny, and knowledge deficiencies have been found to act as barriers to prescribing CR opioids for CNMP. However, these are not the only barriers. Other factors such as physician gender, ethnicity, experience, practice type and location may influence physician prescribing of long-acting opiate analgesics for CNMP as well (Weinstein *et al.*, 2000b; Weisse *et al.*, 2001; Probst *et al.*, 2002; Tamayo-Sarver *et al.*, 2003; Weisse *et al.*, 2003; Goli& Finley, 2005).

Gender. For this study, no statistically significant differences existed in attitudes between male and female family physicians. Also, no differences in perceived behavioral control were observed between the two groups. However, significant differences were observed in the social norms between male and female respondents ($t=2.98$, $d.f.=251$, $p=0.003$). Male physicians tended to believe that pain specialty groups would be more supportive in their prescribing of CR opioids for CNMP compared to female physicians. In addition, patients appeared to have more influence among male physicians. Male respondents were more likely to comply with requests from patients seeking CR opioids compared to female physicians. On the other hand, female respondents were more likely to be influenced by other healthcare providers and office staff when considering the prescribing of long-acting opioids for CNMP. There is limited literature available to explain the differences observed between male and female respondents (Weisse *et al.*, 2001; Weisse *et al.*, 2003; Goli& Finley, 2005). Perhaps female physicians are more concerned about the safety issue of placing CNMP patients on long-acting opiates. The Weisse *et al.* (2001) study suggested that potential complications arising from the use of opioids could influence opioid prescribing decisions among female physicians. Further, female physicians may be more comfortable referring patients to a pain specialist rather than prescribing long-acting opiates themselves. Future TPB research should further examine how social influences may affect willingness to prescribe CR opioids for CNMP when physician gender is considered to better understand treatment patterns among male and female physicians.

Ethnicity. This study examined the relationship between physician ethnicity and the TPB constructs affecting willingness to prescribe. Statistically significant differences existed in physician ethnicity among the mean scores for indirect (belief-based) attitude

($F_{3,242}$=2.83, p=0.039) and subjective norm ($F_{3,247}$=2.89, p=0.036). It should be noted that because of the low number of African-American respondents, this ethnic group was collapsed into the "other" category. With that in mind, the study found white family physicians to hold more positive attitudes toward prescribing CR opioids for CNMP when compared to respondents in the "Other" category. Latino respondents were observed to have significantly higher subjective norm scores compared to Asians, indicating that Latino physicians felt they had more positive social influences supporting their prescribing behaviors compared to Asian physicians. Given the relatively low sample size of ethnic minority respondents, these results should be interpreted with caution. Future TPB research examining physician willingness should employ sampling techniques that allow for an adequate sample size of ethnic minority groups.

Years Experience. Based on the literature, it was assumed that less experienced (i.e., junior level) family physicians would be influenced to a greater extent by outside social factors such as colleagues and experts when it came to their willingness to prescribe (Limbert& Lamb, 2002). Though the results of the study showed a negative correlation between direct attitudes and years of practice experience, the study found, no statistically significant differences between years of experience and willingness. Nor did significant differences exist in the mean scores of the other direct or indirect measures of the TPB constructs.

Geographic Location. It was hypothesized that family physicians practicing in suburban areas would have significantly more favorable attitudes toward prescribing CR opioids for moderate to severe CNMP (compared to physicians in urban or rural areas). Previous studies have found that physician respondents practicing in rural areas generally hold more negative views toward opioids compared to physicians in larger communities (Weinstein *et al.*, 2000; Probst *et al.*, 2002). However, in this study no significant differences in attitudes among physicians practicing in suburban, urban, or rural areas were found. Furthermore, no differences existed in the mean scores of the subjective norm construct or perceived behavioral constructs based on physician practice location.

Practice Type. No differences were found in type of practice and the TPB constructs. It was expected that significant differences in subjective norm would be observed between family physicians in solo and partner/group practices. However, no substantial differences were observed in the mean scores for this construct.

6.3 Study Model

The TPB model was considered to be a relatively good predictor of family physicians' willingness to prescribe. Similar to Nash *et al.'s* (1993) previous research findings examining health providers' intentions (R^2=21, p<0.001) to use opioids, the TPB model for this study explained a significant amount of variance (R=0.62, p<0.001). As hypothesized, the TPB (attitude + subjective norm + perceived behavioral control) accounted for more variation (39 percent) in physicians' willingness compared to the TRA model (attitude + subjective norm) which explained 36 percent. These findings show that the addition of the perceived behavioral control construct significantly improved the explanatory power of the TPB model (R^2 change=0.03, F Change $_{1,222}$=12.37, p<0.001) when compared to only using the attitude and subjective norm constructs (refer to section 5.11). These findings further support the argument that the TPB is a more appropriate model to assess behaviors that are considered not to be under full volitional control (i.e., prescribing CR opioids).

As discussed in previous sections, both direct and indirect TPB constructs explained significant amounts of variance in physicians' willingness to prescribe CR opioids for CNMP. This study was particularly geared towards understanding the indirect (belief-based) constructs. Attitude, subjective norm, and perceived behavioral control were all found to be significant predictors of willingness to prescribe. Results of the analyses showed beta weights for indirect attitude (β=0.41, p<0.001), social norms (β=0.20, p<0.001), and perceived behavioral control (β=0.20, p<0.001) to significantly explain physician' willingness to prescribe CR opioids for CNMP. The addition of the recent past behavior variable significantly improved the explanatory power of the TPB model, accounting for 57 percent of the variance in willingness (R^2 change=0.18, F Change $_{1,221}$=88.85, $p<0.001$). Findings are similar to results from other TPB physician studies that showed inclusion of past behavior to the model significantly increased the proportion of variance explained by the TPB (Millstein, 1996; Walker *et al.*, 2001). Beta weights for the final TPB model showed belief-based attitude (β=0.25, $p<0.001$), subjective norm (β=0.10, $p<0.001$), perceived behavioral control (β=0.17, $p<0.001$), and recent past behavior (β=0.48, $p<0.001$) to be relatively strong predictors. In all, findings for this study reinforce Ajzen's (1991) premise that past behavior can provide important information with regard to future behavior when using the TPB model.

6.4 Limitations

This study was subject to a number of limitations. As with many surveys, because of the low response rate (10% response) and limited sample, data from the questionnaire should be interpreted with some caution. Since this was a cross-sectional study, all data were collected at one point in time, and, as a result, causality among variables cannot be determined. Therefore, interpretation of the findings should not assume a causal relationship between the TPB variables being examined and willingness to prescribe CR opioids to patients with moderate to severe CNMP. The survey was sent to TAFP members. Therefore, caution should be taken when attempting to extrapolate these results to family physicians or other primary care physicians outside the TAFP organization. Moreover, since this was a voluntary survey, results may be skewed and not be representative of all TAFP members. Due to the sensitive nature of the topic, social desirability bias may have occurred, which may have led respondents to modify their actual responses to demonstrate that they are not over-prescribing controlled substance or under treating their patients who suffer from CNMP. Further, clarification on the specific types of moderate to severe CNMP may have been useful in helping physicians to assess questionnaire items. Since this was an electronic web-based survey, selection bias may have occurred among physicians who were more technologically inclined or have ready access to a computer and the internet. As a result, this web-based survey technique may have excluded potential participants who normally respond to traditional paper-based surveys (i.e., postal and fax surveys). Not all physicians may have received the electronic survey. E-mail addresses used to contact physicians may have been incorrect or out-dated. Physicians may have had e-mail filters that blocked unwanted solicitations or what is considered “spam.” In addition, physician “gatekeepers,” such as receptionists, office managers, nurses, and other staff members may have screened physician e-mail communications to protect doctors from unwanted intrusions of their time (Olmsted *et al.*, 2005). There was also the potential for gatekeepers to fill out the survey themselves. The length of the questionnaire instrument (over 60 question items) may have affected overall response rate and survey completion.

Not all salient belief items may have been identified. Focus group interviews may not have captured the most readily available salient beliefs held among the target population. In addition, scales used to measure the direct TPB construct, subjective norm, only consisted of one item. Though there is no set method to construct this scale, it may have been more appropriate to include several direct measure-items that better assessed the *injunctive* and *descriptive* qualities to enhance the variability associated with each item (Ajzen, 2002b). Historical and maturation bias may have occurred. Since focus groups were held several months prior to the administration of the survey, the general viewpoints of the target population may have changed during that time period (due to new pain guidelines, opioid regulatory changes, or personal experience).

6.5 Future Research

This study attempted to identify factors that influence family physicians’ willingness to use long-acting opioids for moderate to severe CNMP. As this was an exploratory study, it should be understood that not all factors influencing physician willingness were identified. Nevertheless, information gathered from this study should be disseminated among family physicians and the medical community in effort to educate health practitioners on the potential barriers associated with prescribing long-acting opioids to their CNMP patients.

As with all empirical research, a need exists to validate the findings of this study among other family physician groups. Therefore, additional studies should be conducted to determine the generalizability of results among family physicians practicing in Texas and other states. As the scope of this study was restricted to Texas family physicians, future research could be performed to ascertain how willingness to prescribe CR opioids for CNMP may differ among other primary care physicians, such as internists and general practitioners. However, additional studies should not be limited to physicians only. Physician assistants and nurse practitioners also play a critical role in the delivery of care to patients with chronic pain. Depending on their state of residence, a number of these professionals have been granted controlled-substance prescribing privileges under a supervising physician. It would be interesting to see how identified factors may influence their willingness to use or administer CR opioids among CNMP patients.

There is much debate about the validity of the TPB model, particularly whether willingness (behavioral intention) leads to the actual behavior. As a follow-up to this study, future research should examine the links between willingness to prescribe CR opioids and future prescribing behavior. Further, longitudinal studies should be designed to assess the impact of educational interventions on willingness and monitor the effects of these interventions on actual prescribing behavior. These future studies could be used to develop a more comprehensive TPB model that would be more useful in assessing practitioners' willingness to prescribe CR opioids for chronic pain conditions.

6.6 Conclusion

This research is among the first to use a theoretical model to examine physicians' willingness to prescribe long-acting opioids for moderate to severe CNMP. Through the use of the Theory of Planned Behavior, factors influencing family physicians' willingness to prescribe CR opioids for CNMP were identified and tested. The results of the present study showed a majority of Texas family physicians were willing to prescribe CR opioids for CNMP. However, a significant number of family physicians indicated that they were unwilling to prescribe this type of opiate analgesic. The TPB model and RPB accounted for 57 percent of the variance in explaining physicians' willingness to prescribe CR opioids for CNMP and all three TPB constructs (attitude + subjective norm + perceived behavioral control) and RPB were found to be significant predictors of willingness. Given the current level of interest in improving pain management among patients with CNMP, information presented in this study could be used to build interventions that focus on improving physicians' standard of care when it comes to treating CNMP patients with CR opioids. Additional research using the TPB could be informative in identifying the underlying causes of physician's willingness to prescribe long-acting opiates for CNMP.

APPENDIX A
Interview Guide:
Focus Group Questions

Focus Group Cover letter

Introduction
My name is Esmond Nwokeji and I will be your moderator for this focus group session. The purpose of this focus group session is to get your perceptions, and experiences regarding the use of schedule II controlled released opioids (CR-Opioids) to treat patients suffering from moderate to severe chronic non-malignant pain (CNMP). The information obtained from this focus group session will be used to develop an anonymous survey that will be administered to the Texas Academy of Family Physicians (TAFP) members.

This session will be audio (cassettes) recorded. However, no names will be used for any portion of the larger study. Information obtained from this focus group session will not be associated with any specific focus group participant. The purpose of the audio recordings during the focus group session is to ensure that no important information is missed when constructing the final survey instrument. The cassettes will be coded so that no personally identifying information is visible on them. Cassettes will be stored in a locked file cabinet in the investigators office and will be heard only for research purposes by the investigator and his or her research associates. The audio recordings will be destroyed at the completion of the study.

This session is expected to last one to two hours and you have the right to stop participating at any time.

Group Rules
As the moderator, I will ask the questions and keep everyone on track. I will keep track of time, and therefore, I may need to interrupt the discussion and move forward if I see we are getting short on time. It is important that everyone feels comfortable during the discussion. There are no right and wrong answers. Everyone's input is vital. I encourage you to speak freely and openly about the issues discussed during this session.

General Questions
1. Briefly tell me what you think about when you think of prescribing CR-Opioids to treat patients with moderate to severe (CNMP).

2a. What comes to mind when you hear "How willing are you to prescribe CR-Opioids to patients with CNMP?"

2b. How does this question differ from "How likely are you to prescribe CR-Opioids to patients with CNMP?" and "Do you intend to prescribe CR-Opioids to patients with CNMP?"

Texas Academy of Family Physicians Focus Group

Focus Group Questions

1. What do you think are some of the advantages associated with FPs prescribing controlled released opioids (CR-Opioids) to treat patients with moderate to severe chronic non-malignant pain (CNMP)?

2. What do you think are some of the disadvantages associated with FPs prescribing CR-Opioids to treat patients with moderate to severe CNMP?

3. Are there any other advantages and disadvantages associated with FPs prescribing CR-Opioids to treat patients with moderate to severe CNMP?

4. Are there any individuals or groups who would approve of FPs prescribing CR-Opioids to treat patients with moderate to severe CNMP?

5. Are there any individuals or groups who would not approve of FPs prescribing CR-Opioids to treat patients with moderate to severe CNMP?

6. Are there any other individuals or groups who would or would not approve FPs prescribing CR-Opioids to treat patients with moderate to severe CNMP?

Focus Group Questions (cont'd)

7. What do you think would make it easier for FPs prescribing CR-Opioids to treat patients with moderate to severe CNMP?

8. What do you think would make it more difficult for FPs prescribing CR-Opioids to treat patients with moderate to severe CNMP?

9. Are there any other factors you think would make it easier or more difficult for FPs prescribing CR-Opioids to treat patients with moderate to severe CNMP?

APPENDIX B
Survey Cover Letters

Pre-notification E-mail

Dear Dr. X,

Within the next few days, you will receive a request to participate in an anonymous online web survey that is being conducted by the University of Texas in cooperation with TAFP-SPARCC.

The purpose of the study is to survey family physicians' attitudes and views regarding the use of controlled-release opiate analgesics to treat patients with chronic non-malignant pain (CNMP) in an effort to learn more about factors (e.g., concerns of patient addiction, illicit usage, and regulatory scrutiny) that may affect a physicians willingness to use controlled release opioids for patients with CNMP.

We sincerely hope that you choose to participate in this important study. If you have questions about the survey, please contact either Paige Newman at e-mail pnewman@tafp.org (phone: 512-329-8666 ext 35) or Esmond Nwokeji at esmondn@mail.utexas.edu. Thank you in advance for your help.

Sincerely,

Esmond D. Nwokeji, PhD student, University of Texas at Austin, College of Pharmacy

Andrew Eisenberg, M.D. MHA, TAFP Member, SPARCC, Dissertation Committee Member

E-mail Cover Letter

Dear Dr. X,

The University of Texas in cooperation with the TAFP-SPARRC is conducting an anonymous online survey to examine our TAFP members' attitudes and views toward long-acting opiate analgesics to treat patients with chronic non-malignant pain (CNMP).

As an active TAFP member, your name was selected from the TAFP membership database to participate in this important study. The purpose of this study is to better understand how factors such as, concerns of patient addiction, illicit use and regulatory scrutiny can influence FPs decisions to prescribe long-acting opiates for CNMP patients. Information gathered from the study may be used by FPs and health organizations to better meet the needs of their CNMP patients within the community.

This survey is coordinated by a PhD student at The University of Texas at Austin, College of Pharmacy, in cooperation with the TAFP-SPARRC. You may be assured that your responses to the electronic questionnaire are anonymous and no personally identifiable information will be collected. This voluntary online questionnaire takes approximately xx minutes to complete. Please complete the survey by day, month XX.

To BEGIN THE SURVEY or learn more about the study, please visit the following URL: http://www.tafp/tobedetemined/CNMPsurvey/

We sincerely hope that you choose to participate in this important study. If you have questions about the survey, please contact either Paige Newman at e-mail pnewman@tafp.org (phone: 512-329-8666 ext 35) or Esmond Nwokeji at esmondn@mail.utexas.edu.

Thank you in advance for your time and cooperation in participating in this important study.

Sincerely,

Esmond D. Nwokeji, PhD Candidate, University of Texas at Austin, College of Pharmacy

Andrew Eisenberg, M.D. MHA, TAFP Member, SPARCC, Dissertation Committee Member

Follow-up E-mail

Dear TAFP Member,

About two weeks ago, you should have received an e-mail asking for your participation in an anonymous online web-survey. The purpose of this study is to better understand how factors such as, concerns of patient addiction, illicit use and regulatory scrutiny can influence FPs decisions to use long-acting opioids among patients with chronic non-malignant pain. The results of the study can be used by FPs and public health officials to better meet the needs of their patients who suffer from chronic pain.

If you have already completed the anonymous questionnaire, please accept our sincere thanks. If you have not yet completed the electronic questionnaire, we kindly ask for your assistance by completing it as soon as possible. As an active TAFP member and a practicing family physician, your responses are important to us. A link to the survey questionnaire can be found below.

Please go to the following URL to complete the survey:
http://www.tafp/tobedetemined/CNMPsurvey/

We sincerely hope that you choose to participate in this important study. If you have questions about the survey, please contact either Paige Newman at e-mail pnewman@tafp.org (phone: 512-329-8666 ext 35) or Esmond Nwokeji at esmondn@mail.utexas.edu. Thank you in advance for your help.

Thank you in advance for your time and cooperation in participating in this academic research study.

Sincerely,

Esmond D. Nwokeji, PhD Candidate, University of Texas at Austin, College of Pharmacy

Andrew Eisenberg, M.D. MHA, TAFP-SPARCC, Dissertation Committee Member

APPENDIX C
Online Consent Form

SPARRC
THE TAFP RESEARCH NETWORK
The Statewide Primary Care Ambulatory Research and Resourse Consortium

Online Consent Form- Physician Attitude Survey

The purpose of the study is to better understand factors (i.e., attitudes, social influences, and control beliefs) that can affect family physicians' pain management decision making-- particularly when it involves the use of long-acting opiates to treat patients with chronic non-malignant pain (CNMP). Information gathered from the study can be used to better meet the educational needs of primary care providers and ultimately the needs of their CNMP patients within the community.

This anonymous survey is expected to take about 10 - 12 minutes to complete. Before proceeding on to the survey, please read the following online consent information then click on the "I Agree" button below. For a printable copy of the online consent form click here.

ONLINE CONSENT

TITLE:
Examining the attitudes and beliefs of family physicians toward the use of controlled-release opioids for the treatment of chronic non-malignant pain.

IRB PROTOCOL # 2005-04-0101

CONDUCTED BY:
Esmond D. Nwokeji, Ph.D. student, The University of Texas at Austin, College of Pharmacy (UTCOP);
Andrew Eisenberg, M.D. MHA, TAFP Member, SPARCC, Dissertation Committee Member;

I AGREE

If you would like to contact the coordinators of the survey, please email Paige Newman at pneman@tafp.org (phone 512.329.8666 ext.35) or Esmond D. Nwokeji at esmondn@mail.utexas.edu or mail: ATTN: Esmond Nwokeji, The University of Texas at Austin, College of Pharmacy, 2409 University Avenue, 1 University Station A1900, Austin TX 78712-0127.

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(Text from above web page's online consent form scrolling text box)

ONLINE CONSENT FORM

TITLE:
Examining the attitudes and beliefs of family physicians toward the use of controlled-release opioids for treating patients suffering from chronic non-malignant pain.

IRB PROTOCOL # 2005-04-0101

CONDUCTED BY:
Esmond D. Nwokeji, PhD student, The University of Texas at Austin, College of Pharmacy (UTCOP);
Andrew Eisenberg, M.D. MHA, TAFP Member, SPARCC, Dissertation Committee Member;
Carolyn M. Brown, Ph.D., Associate Professor and Dissertation Co-supervisor, UTCOP; and
Dr. Karen L. Rascati, PhD., Professor and Dissertation Co-supervisor, UTCOP.

University of Texas at Austin: Pharmacy Administration Dept; Telephone (512) 471-6892.

You are being asked to participate in a research study. This form provides you with information about the study. The person in charge of this research can also describe this study to you and answer all of your questions. Please read the information below and call or e-mail your questions about anything you don't understand before deciding whether or not to take part. Your participation is entirely voluntary and you can refuse to participate without penalty or loss of benefits to which you are otherwise entitled. You can stop your participation at any time.

THE PURPOSE OF THIS STUDY is to better understand how factors such as, "concerns of patient addiction, illicit use and regulatory scrutiny" can influence FPs decisions to use long-acting opioids among patients with chronic non-malignant pain (CNMP). THE RESULTS of the study can be used by FPs and public health officials to better meet the needs of their patients who suffer from chronic pain.

Go to http://www.tafp.org/SPARRC/Opioid_Pain_study.htm for more information on background of study

IF YOU AGREE TO BE IN THIS STUDY, WE WILL ASK YOU TO DO THE FOLLOWING THINGS:
1. complete a 1 page electronic questionnaire on your views toward long-acting opioids used to treat patients with chronic non malignant pain
2. complete general demographic/practice information (year graduated, practice size, etc.)

TOTAL ESTIMATED TIME to participate in study is 10 to 15 minutes

RISK AND BENEFITS of being in the study:
1. no personally identifiable information will be collected from you
2. there are no benefits but summary information will be available on the TAFP website when the study is complete

COMPENSATION:
1. No compensation is provided for this study

The RECORDS of this study will be stored securely and kept private. Authorized persons from The University of Texas at Austin, members of the Institutional Review Board, and TAFP have the legal right to review research records and will protect the CONFIDENTIALITY of those records to the extent permitted by law. All publications will exclude any information that will make it possible to identify you as a subject. The information gathered from this survey will be used for academic purposes only and will be shared and published with TAFP in aggregate form only.

This STUDY has received NO OUTSIDE FUNDING and is supported by the TAFP.

CONTACTS AND QUESTIONS:
If you have any questions about the study please ask now. If you have questions later or want additional information, call the researchers conducting the study. Their names, phone numbers, and e-mail addresses are at the bottom of this page.

If you have questions about your rights as a research participant, please contact Clarke A. Burnham, Ph.D., Chair, The University of Texas at Austin Institutional Review Board for the Protection of Human Subjects, (512) 232-4383.

Please print a copy of this information to keep for your records.

STATEMENT OF CONSENT:
I have read the above information and have sufficient information to make a decision about participating in this study. I consent to participate in the study.

Answering questions on the electronic questionnaire will serve as your consent to participate in the study.

Click on the "I Agree" button to begin the survey.

APPENDIX D
Electronic Questionnaire

SPARRC
THE TAFP RESEARCH NETWORK
The Statewide Primary Care Ambulatory Research and Resourse Consortium

TAFP Attitude Survey

This TAFP/ University of Texas study is interested in learning more about family physicians' attitudes toward prescribing long-acting opiate analgesics to treat patients with moderate to severe chronic non-malignant pain (CNMP). In this survey, we ask that you respond to questions that best reflect your views.

Definition of long-acting opiate analgesics- Also known as "sustained-release" or "controlled-release" opioids, this group of analgesics is considered to provide analgesia in the same manner as immediate-release (short-acting) opioids but over longer periods of time. This class of drug Includes morphine sulfate, oxycodone, methadone, transdermal fentanyl, levorphanol, and hydromorphone.

Section I. Willingness

Please rate your level of willingness with the following statement. (click on the appropriate button below)

Question 1 - Willingness (W) scored using a bipolar response scale (-3 to +3)

I am willing to prescribe long-acting opioids to treat patients with moderate to severe chronic non-malignant pain (CNMP).

extremely unlikely	quite unlikely	somewhat unlikely	neither likely nor unlikely	somewhat likely	quite likely	extremely likely
○	○	○	○	○	○	○

<< Back   click on "Next" to go to Question 2   Next >>

Section II. Attitudes

The list below are possible outcomes (mentioned by other TAFP members) which may result from prescribing long-acting opioids for CNMP.

Question 2 - Behavioral beliefs (b_{1-10}) scored using a bipolar response scale (-3 to +3)

How likely do you think the following outcomes will occur if you prescribe long-acting opioids to patients with moderate to severe CNMP?

	extremely unlikely	quite unlikely	somewhat unlikely	neutral	somewhat likely	quite likely	extremely likely
a. will lead to abusive drug behaviors (e.g., drug seeking, illicit use)	○	○	○	○	○	○	○
b. will require additional patient history	○	○	○	○	○	○	○
c. will lengthen patient office visits	○	○	○	○	○	○	○
d. will be effective in controlling pain	○	○	○	○	○	○	○
e. will improve the patients' quality-of-life	○	○	○	○	○	○	○
f. will be less expensive compared to other short-release drugs	○	○	○	○	○	○	○
g. will make it difficult to manage those patients on multiple medications	○	○	○	○	○	○	○
h. will make it difficult to manage patients with co-morbidities	○	○	○	○	○	○	○
i. will lead to increased regulatory scrutiny	○	○	○	○	○	○	○
j. will lead to patient addiction	○	○	○	○	○	○	○

<< Back click on "Next" to go to Question 3 Next >>

Question 3 - Outcome evaluation (e_{1-10}) scored using a bipolar response scale (-3 to +3)

Even though you may not agree with outcomes listed, how good or bad do you feel each of the following outcomes (if they occurred) would be if you prescribed long-acting opioids to treat patients with moderate to severe CNMP?

	extremely bad	quite bad	somewhat bad	neutral	somewhat good	quite good	extremely good
a. abusive drug behaviors (e.g., drug seeking, illicit use)	○	○	○	○	○	○	○
b. requirement of additional patient history	○	○	○	○	○	○	○
c. lengthened patient office visits	○	○	○	○	○	○	○
d. effectiveness in controlling pain	○	○	○	○	○	○	○
e. improvement of the patients' quality-of-life	○	○	○	○	○	○	○
f. less expense compared to other short-release drugs	○	○	○	○	○	○	○
g. difficulty in managing patients on multiple medications	○	○	○	○	○	○	○
h. difficulty in managing patients with co-morbidities	○	○	○	○	○	○	○
i. increased regulatory scrutiny	○	○	○	○	○	○	○
j. patient addiction	○	○	○	○	○	○	○

<< Back click on "Next" to go to Question 4 Next >>

Question 4 - Direct Attitude scored using a bipolar response scale (-3 to +3)

Please rate the following statement based on each of the following adjectives.

"I feel that prescribing long-acting opiates to patients with moderate to severe CNMP is..."

very bad	○	○	○	○	○	○	○	**very good**
very harmful	○	○	○	○	○	○	○	**very beneficial**
very useless	○	○	○	○	○	○	○	**very useful**
very foolish	○	○	○	○	○	○	○	**very wise**
very worthless	○	○	○	○	○	○	○	**very valuable**

<< Back click on "Next" to go to Question 5 **Next >>**

Section III. Social Influences

Please rate whether you believe the following persons or groups think you should or you should not prescribe long-acting opiods to CNMP patients.

Question 5 - Normative beliefs (n_{1-7}) scored using a bipolar response scale (-3 to +3)

How likely is it that each of the following individuals or groups would think that you should prescribe long-acting opioids to patients with moderate to severe CNMP?

	extremely unlikely	quite unlikely	somewhat unlikely	neutral	somewhat likely	quite likely	extremely likely
a. regulatory agencies	○	○	○	○	○	○	○
b. other primary care physicians	○	○	○	○	○	○	○
c. consumer groups	○	○	○	○	○	○	○
d. pain specialty physicians	○	○	○	○	○	○	○
e. patients	○	○	○	○	○	○	○
f. Texas Medical Board	○	○	○	○	○	○	○
g. other healthcare providers and staff (e.g., physician assistants, nurses, and pharmacists)	○	○	○	○	○	○	○

<< Back click on "Next" to go to Question 6 Next >>

Question 6 - Motivation to comply (m_{1-7}) scored using a bipolar response scale (-3 to +3)

Generally speaking, how likely are you to do what the following individuals or groups want you to do when prescribing long-acting opiates to patients with moderate to severe CNMP?

	extremely unlikely	quite unlikely	somewhat unlikely	neutral	somewhat likely	quite likely	extremely likely
a. regulatory agencies	○	○	○	○	○	○	○
b. other primary care physicians	○	○	○	○	○	○	○
c. consumer groups	○	○	○	○	○	○	○
d. pain specialty physicians	○	○	○	○	○	○	○
e. patients	○	○	○	○	○	○	○
f. Texas Medical Board	○	○	○	○	○	○	○
g. other healthcare providers and staff (e.g., physician assistants, nurses, and pharmacists)	○	○	○	○	○	○	○

go to Question 7 (below)

Question 7 - Direct subjective norm scored using a bipolar response scale (-3 to +3)

If I prescribe long-acting opioids for patients with moderate to severe CNMP, most people who are important to me would approve:

strongly disagree	somewhat disagree	slightly disagree	neutral	slightly agree	somewhat agree	strongly agree
○	○	○	○	○	○	○

<< Back click on "Next" to go to Question 8 Next >>

Section IV. Control Factors

Below are factors that you may perceive make it easier or more difficult to prescribe long-acting opiate analgesics to patients with CNMP.

Question 8 - Control beliefs (c_{1-10}) scored using a bipolar response scale (-3 to +3)

Will the following factors make it easy or difficult for you to prescribe long-acting opioids to patients with moderate to severe CNMP:

	extremely difficult	quite difficult	somewhat difficult	neutral	somewhat easy	quite easy	extremely easy
a. more knowledge in pain management	○	○	○	○	○	○	○
b. access to pain management tools	○	○	○	○	○	○	○
c. writing triplicate prescriptions	○	○	○	○	○	○	○
d. managing patients who are on multiple medications	○	○	○	○	○	○	○
e. full compensation for services associated with prescribing long-acting opioids	○	○	○	○	○	○	○
f. access to multidisciplinary teams	○	○	○	○	○	○	○
g. ready access to patient medical records	○	○	○	○	○	○	○
h. more evidence-based studies	○	○	○	○	○	○	○
i. managing patients who have co-morbidities	○	○	○	○	○	○	○
j. less regulatory scrutiny	○	○	○	○	○	○	○

<< Back click on "Next" to go to Question 9 Next >>

Question 9 - Perceived power (p_{1-10}) scored using a unipolar response scale (1 to 7)

How much control do you feel you have over the following when it comes to prescribing long-acting opioids to patients with moderate to severe CNMP?

	no control	slight control	little control	some control	more control	a lot of control	complete control
a. more knowledge in pain management	○	○	○	○	○	○	○
b. access to pain management tools	○	○	○	○	○	○	○
c. writing triplicate prescriptions	○	○	○	○	○	○	○
d. managing patients who are on multiple medications	○	○	○	○	○	○	○
e. full compensation for services associated with prescribing long-acting opioids	○	○	○	○	○	○	○
f. access to multidisciplinary teams	○	○	○	○	○	○	○
g. ready access to patient medical records	○	○	○	○	○	○	○
h. more evidence-based studies	○	○	○	○	○	○	○
i. managing patients who have co-morbidities	○	○	○	○	○	○	○
j. less regulatory scrutiny	○	○	○	○	○	○	○

<< Back   click on "Next" to go to Question 10   Next >>

Question 10 - Direct perceived behavioral control scored using a bipolar response scale (-3 to +3)

It is easy for me to prescribe long-acting opioids to treat patients with moderate to severe CNMP.

strongly disagree	somewhat disagree	slightly disagree	neutral	slightly agree	somewhat agree	strongly agree
○	○	○	○	○	○	○

go to Question 11

Question 11 - Direct perceived behavioral control scored using a bipolar response scale (-3 to +3)

I have complete control over whether or not I will prescribe long-acting opioids for patients with moderate to severe CNMP.

strongly disagree	somewhat disagree	slightly disagree	neutral	slightly agree	somewhat agree	strongly agree
○	○	○	○	○	○	○

<< Back   click on "Next" to go to Question 12   Next >>

Section V. Past Behavior

Question 12 - Recent past behavior scored using a bipolar response scale (1 to 7)

How often have you prescribed long-acting opioids to patients with moderate to severe CNMP in the last month?

never ○ ○ ○ ○ ○ ○ ○ **always**

<< Back click on "Next" to go to Question 13 Next >>

Section VI. Demographics and Practice Setting

Question 13

Are you board certified?

○ yes ○ no

Question 14

How many years have you been a practicing physician?

[ ] years (enter in box)

Question 15

What is your gender?

○ male ○ female

Question 16

Which of the following best describes your ethnic/racial background?

Please select from list

1=African American/Black
2=Asian or Pacific Islander
3=Latino/Latin American Hispanic
4=Native American/Indigenous Peoples
5=White/European American
6=Other

Question 17

Which of the following best describes your primary practice location?

Please select from list

1=Urban
2=Suburban
3=Rural

Question 18

Which of the following best describes your type of practice?

Please select from list

1=Solo Practice
2=Partnership Practice
3=Physician Group
4=Managed Care
5=Hospital or Clinical Institution
6=Other

Question 19

On average, how many CNMP patients do you see a week?

(enter in box)

Question 20 - Recent past behavior scored using a bipolar response scale (1 to 5)

How often do you prescribe long-acting opioids to patients with moderate to severe CNMP?

Please select from list

1=Never
2=Sometimes
3=About Half the Time
4=Most of the Time
5=Always

<< Back click on "Next" to go to Question 21 Next >>

Section VII. Continuing Medical Education

Question 21

Have you received any continuing medical education (CME) in chronic pain management in the last three years?

○ yes ○ no

Question 22 - Continuing Medical Education scored using a bipolar response scale (-3 to +3)

Please rate the following statement:

"I feel that I have access to CME courses in chronic pain management."

strongly disagree	somewhat disagree	slightly disagree	neutral	slightly agree	somewhat agree	strongly agree
○	○	○	○	○	○	○

Question 23 - Continuing Medical Education scored using a bipolar response scale (-3 to +3)

How likely would you be to attend chronic pain management CME activities in the next year?

extremely unlikely	quite unlikely	slightly unlikely	neither	slightly likely	quite likely	extremely likely
○	○	○	○	○	○	○

Question 24 - Continuing Medical Education scored using a bipolar response scale (-3 to +3)

How likely would you be to attend chronic pain management CME activities offered by TAFP?

extremely unlikely	quite unlikely	slightly unlikely	neither	slightly likely	quite likely	extremely likely
○	○	○	○	○	○	○

Question 25

How would you prefer to receive CME in chronic pain management?

Please select from list

1=Onsite Location
2=Monograph
3=Internet
4=Other electronic media (CD, tape, etc)
5=Never

Section VIII. Comments

Question 26

Please enter any comments or suggestions you may have.

THE END

Press the "Submit" button below to submit your responses

Submit Survey

Thank you for your participation!

If you would like to receive an aggregate summary of the results of this study once it is completed, please email Paige Newman at pnewman@tafp.org or Esmond D. Nwokeji at esmondn@mail.utexas.edu or send a post card to the following address: ATTN: Esmond D. Nwokeji, The University of Texas at Austin, College of Pharmacy, 2409 University Avenue, 1 University Station A1900, Austin TX 78712-0127.

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APPENDIX E
Comparison of Demographic/Practice Characteristics
between study sample and 2006 Texas Academy of Family Physician membership population

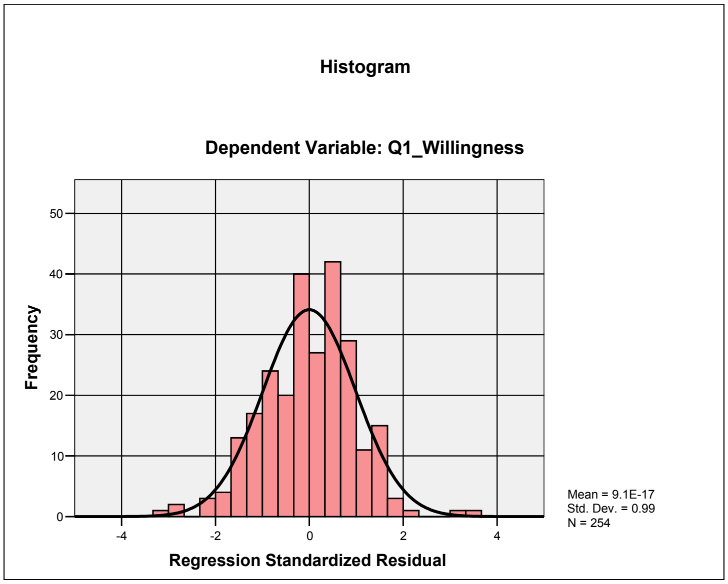
Comparison of demographic and practice characteristics between study sample and 2006 Texas Academy of Family Physician membership population

Demographic/Practice Characteristics	2006 TAFP Active Membership % (N)	2006 TAFP Study Sample % (N)
Gender		
Male	69.7% (2669)	61.8% (165)
Female	30.2% (1158)	36.7% (98)
Missing/Unknown	0.1% (4)	1.5% (4)
Ethnicity		
White/European American	64.8% (2485)	72.7% (194)
Latino/Latin American Hispanic	13.0% (498)	11.6% (31)
Asian or Pacific Islander	12.2% (467)	5.6% (15)
African-American/Black	3.4% (129)	1.9% (5)
Native American/Indigenous Peoples	0.2% (8)	0.0% (0)
Other	N/A[a]	6.0% (16)
Missing/Unknown	6.4% (244)	2.2% (6)
Primary Practice Setting		
Urban/Suburban	84.9% (3224)	69.3% (185)
Rural	15.1% (572)	28.1% (75)
Missing/Unknown	N/A[a]	2.6% (7)
Years Practicing		
0-4 years	14.6% (39)	15.5% (596)
5-9 years	18.4% (49)	20.1% (769)
10-14 years	10.5% (28)	13.8% (528)
15-20 years	16.9% (45)	18.8% (720)
21-24 years	12.0% (32)	10.8% (415)
25-29 years	15.7% (42)	9.7% (372)
30-34 years	5.6% (15)	6.1% (235)
35-39 years	2.2% (6)	2.6% (98)
40+ years	2.2% (6)	2.2% (84)
Missing/Unknown	1.9% (5)	0.4% (14)
Primary Practice Type		
Partnership/ Group	51.5% (1861)	49.8% (133)
Solo Practice	30.2% (1091)	20.2% (54)
Hospital/Military/ Clinical Institution	13.3% (481)	15.4% (41)
Managed Care	1.7% (61)	1.9% (5)
Other	3.3% (120)	10.1% (27)
Missing/Unknown	N/A[a]	2.6% (7)

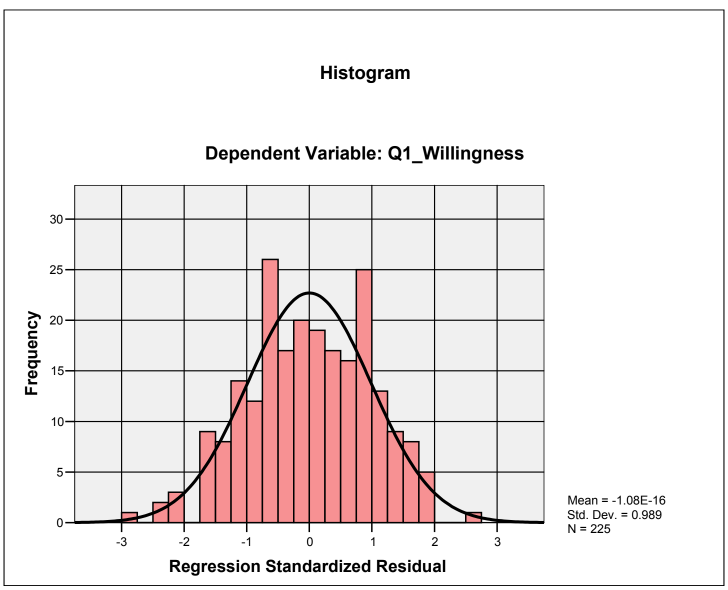
[a]Not Available

APPENDIX F
Histograms Of Residuals From Regression Analysis

Histogram of Residual from Regression of Direct Measure TPB Constructs

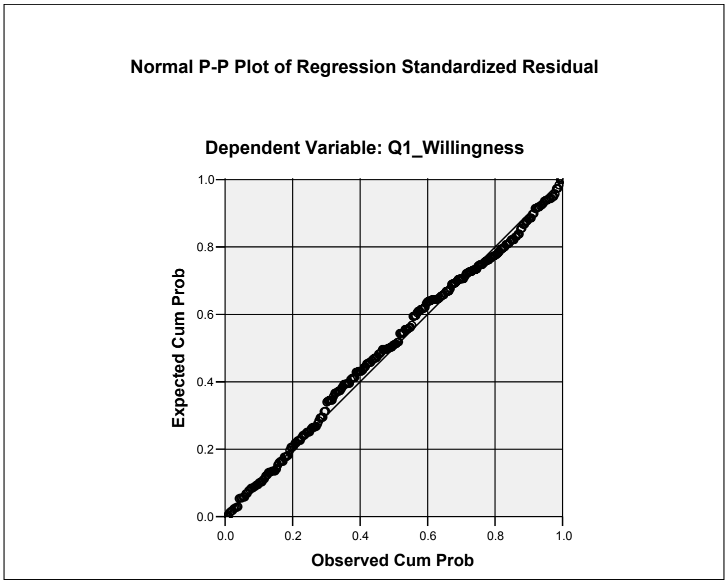


Histogram of Residual from Regression of Indirect (belief-based) Measure TPB Constructs

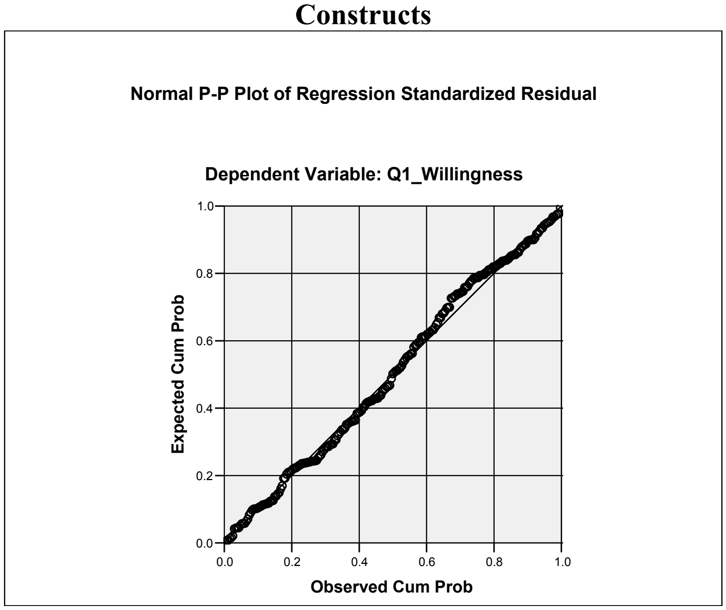


APPENDIX G
Normal P-P Plots

Normal P-P Plot of Regression Standardized Residuals from Direct TPB Constructs

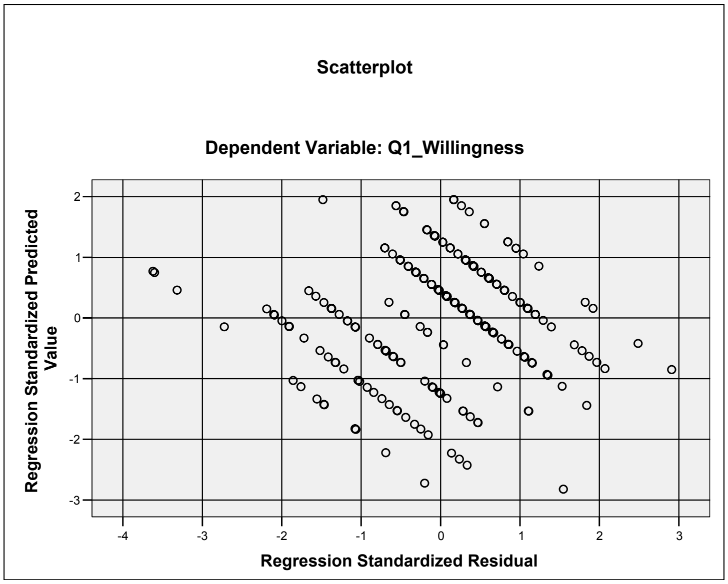


Normal P-P Plot of Regression Standardized Residuals from indirect (belief-based) TPB Constructs

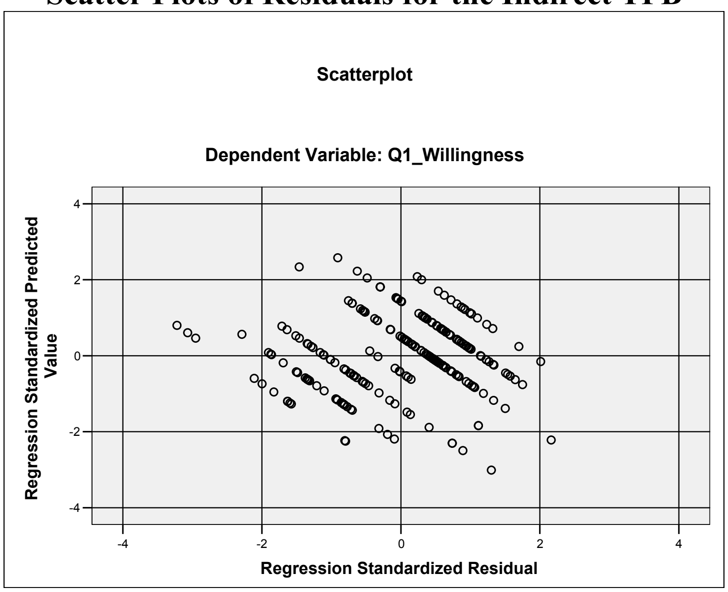


APPENDIX H
Scatter Plots Of Residuals

Scatter Plots of Residuals for the Direct TPB



Scatter Plots of Residuals for the Indirect TPB

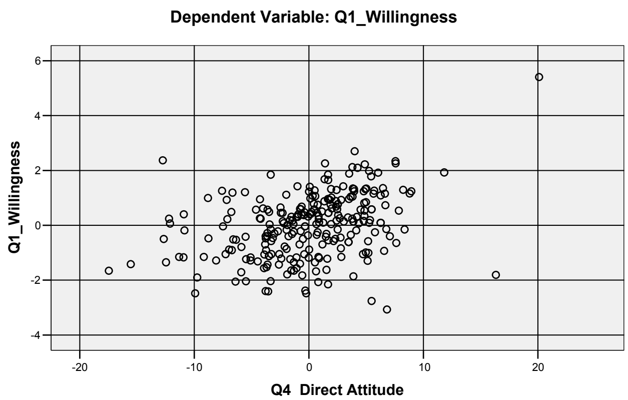


APPENDIX I
Partial Regression Plots

Partial Regression Plots of Direct TPB

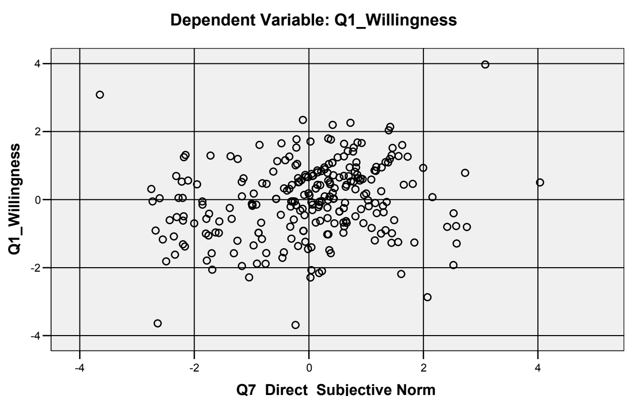
Willingness vs. Direct Attitude

Partial Regression Plot



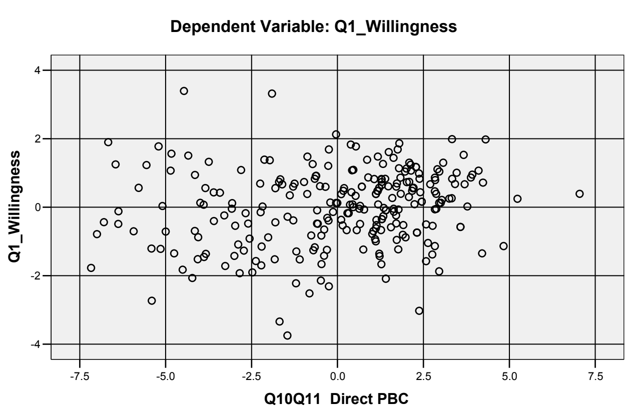
Willingness vs. Direct Subjective Norm

Partial Regression Plot



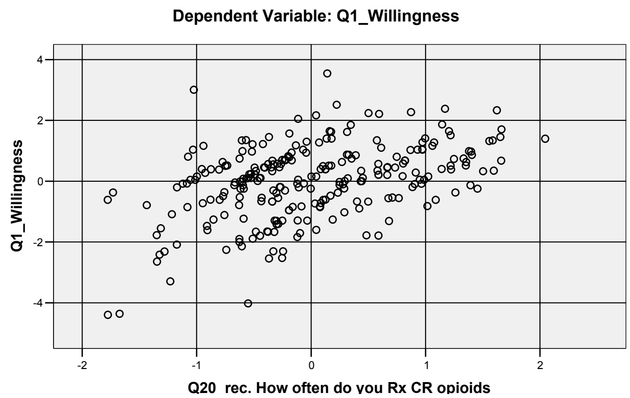
Willingness vs. Direct Perceive Behavioral Control (PBC)

Partial Regression Plot



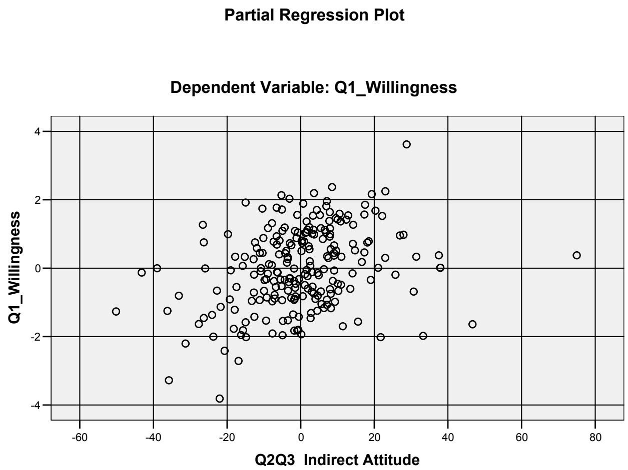
Willingness vs. Recent Past Behavior

Partial Regression Plot

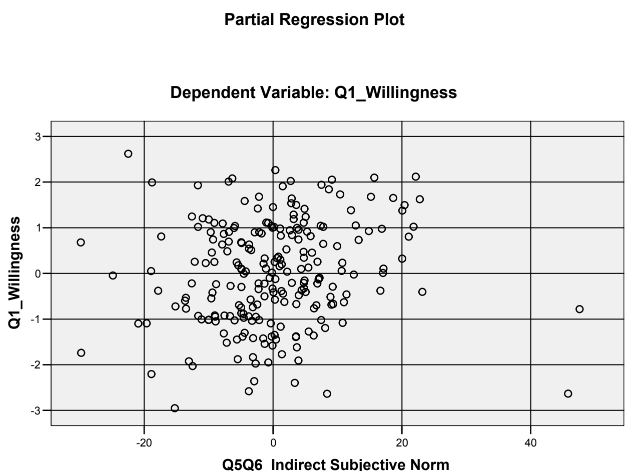


Partial Regression Plots of Indirect TPB

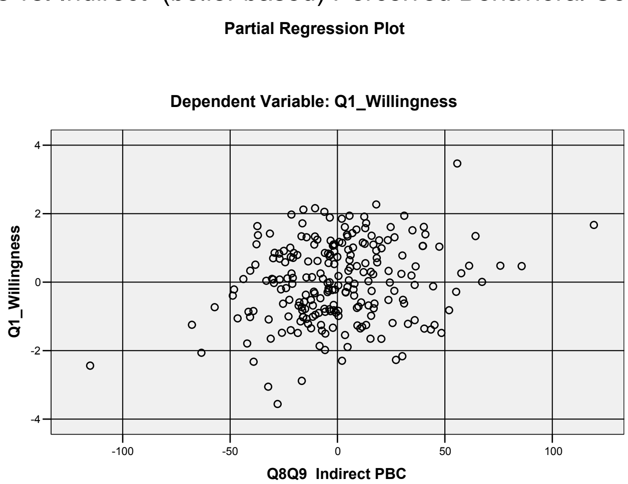
Willingness vs. Indirect (belief-based) Attitude



Willingness vs. Indirect (belief-based) Subjective Norm



Willingness vs. Indirect (belief-based) Perceived Behavioral Control(PBC)



REFERENCES

American Academy of Pain Medicine (AAPM) & American Pain society (APS). (1997). *Definitions Related to the Use of Opioids for the Treatment of Chronic Pain*. Retrieved Nov 8, 2005, from http://www.ampainsoc.org/advocacy/opioids.htm

AGS Panel on Persistent Pain in Older Persons. (2002). The Management of Persistent Pain in Older Persons. *Journal of the American Geriatrics Society, 50*(s1), 205-224.

Ajzen, I. (1985). From intentions to actions: a theory of planned behavior. In In: Kuhl J & B. J (Eds.), *Action control, from cognition to behavior / edited by Julius Kuhl and Jurgen Beckmann.* (pp. 11-39). New York: Springer-Verlag.

Ajzen, I. (1991). The Theory of Planned Behavior. In *Organizational Behavior and Human Decision Processes* (pp. 179-211). New York: Academic Press. Inc.

Ajzen, I. (2002). Residual Effects of Past on Later Behavior: Habituation and Reasoned Action Perspectives. *Personality & Social Psychology Review, 6*(2), 107-122.

Ajzen, I. (2002b). *Constructing a TpB Questionnaire: Conceptual and Methodological Considerations*. Retrieved Dec 29, 2005, from http://www.people.umass.edu/aizen/pdf/tpb.measurement.pdf

Ajzen, I.and Driver, B. (1992). Application of the theory of planned behavior to leisure choice. *Journal of Leisure Research, 24*(3), 207.

Ajzen, I.and Fishbein, M. (1980). *Understanding attitudes and predicting social behavior*. Englewood Cliffs: Prentice-Hall.

Ajzen, I.and Fishbein, M. (2004). Questions raised by a reasoned action approach: Comment on Ogden. *Health Psychology*(23), 431-434.

Ajzen, I.and Madden, T. J. (1986). Prediction of goal-directed behavior: Attitudes, intentions, and perceived behavioral control. *Journal of Experimental Social Psychology, 22*(5), 453-474.

Allan, L., Hays, H., Jensen, N. H., de Waroux, B. L., Bolt, M., Donald, R., and Kalso, E. (2001). Randomised crossover trial of transdermal fentanyl and sustained release oral morphine for treating chronic non-cancer pain. *British Medical Journal, 322*(7295), 1154-1158.

Allegrante, J. P. (1996). The role of adjunctive therapy in the management of chronic nonmalignant pain. *American Journal of Medicine, 101*(1A), 33S-39s.

American Medical Association(AMA). (2004). *About the American Medical Assocation (AMA) Position on Pain Management Using Opioid Analgesics*. Retrieved Dec 17, 2004, from http://www.ama-assn.org/ama/pub/category/print/11541.html

American Academy of Pain Medicine (AAPM)and the American Pain Society (APS). (1997). *Definitions Related to the Use of Opioids for the Treatment of Chronic Pain*. Retrieved Nov 8, 2005, 2005, from http://www.painmed.org/productpub/statements/pdfs/opioids.pdf

American Pain Society. (1995). *Pain: The Fifth Vital Sign*. Retrieved Aug 13, 2005, from http://www.ampainsoc.org/advocacy/fifth.htm

American Pain Society. (2000). *Chronic Pain In America: Roadblocks To Relief. Survey Conducted for the American Pain Society, The American Academy of Pain Medicine and Janssen Pharmaceutica*. Retrieved Dec 17, 2004, from http://www.ampainsoc.org/whatsnew/toc_road.htm#toc

Andersen, S.and Worm-Pedersen, J. (1987). The prevalence of persistent pain in a Danish population. *Pain, Suppl*, S332.

Andersson, G. (1999). Epidemiological features of chronic low-back pain. *Lancet, 354*(9178), 581.

Andersson, H. (1994). The epidemiology of chronic pain in a Swedish rural area. *Quality of Life Research, 3*, S19–S26.

Andersson, H., Eijlertsson, G., Leden, I., and Rosenberg, C. (1993). Chronic pain in a geographically defined general population: studies of differences in age, gender, social class and pain localization. *Clinical Journal of Pain, 9*, 174–182.

Anesthetic and Life Support Drugs Advisory Committee. (2003, Accessed Dec 2004). *Risk Management of Opiate Analgesics.* Paper presented at the Dept of Health and Human Services and the Food and Drug Administration Center for Drug Evaluation and Research.

Angarola, R.and Joranson, D. (1992). State Controlled-Substances Laws and Pain Control. *APS Bulletin, 2*(3), 10-11,15.

Antoin, H.and Beasley, R. D. (2004). Opioids for chronic noncancer pain. Tailoring therapy to fit the patient and the pain. *Postgraduate Medicine, 116*(3), 37.

Argoff, C., Bruckenthal, P., Carmichael, B., Epstein, K., McCarberg, B., and Ray, J. (2005). *Neuropathic Pain*.Unpublished manuscript, Austin, TX.

Arkinstall, W., Sandler, A., Goughnour, B., Babul, N., Harsanyi, Z., and Darke, A. C. (1995). Efficacy of controlled-release codeine in chronic non-malignant pain: a randomized, placebo-controlled clinical trial. *Pain, 62*(2), 169-178.

Armitage, C.and Conner, M. (2001). Efficacy of the Theory of Planned Behaviour: a meta-analytic review. *British Journal of Social Psychology, 40*(Pt 4), 471-499.

Arthritis Foundation. (2003). *Pain in America: highlights from a Gallup survey*. Retrieved Aug 16, 2005, from www.arthritis.org/conditions/speakingofpain/factsheet.asp. http://www.biotherapy-clinic.com/pain.html

Ashburn, M.and Lipman, A. (2004). Pain in Society. In L. AG (Ed.), *Pain Management for Primary Care Clinicians* (pp. 1-12). Bethesda: American Society of Health-System Pharmacists.

Ashburn, M. A.and Staats, P. S. (1999). Management of chronic pain. *Lancet, 353*(9167), 1865-1869.

Bach, P. B., Cramer, L. D., Warren, J. L., and Begg, C. B. (1999). Racial Differences in the Treatment of Early-Stage Lung Cancer. *New England Journal of Medicine, 341*(16), 1198-1205.

Bandura, A. (1991). Social cognitive theory of self-regulation. *Organizational Behavior and Human Decision Processes, 50*(2), 248-287.

Baumann, T. (2002). Pain Management. In J. DiPiro, R. Talbert, G. Yee, G. Matzke, B. Wells & L. Posey (Eds.), *Pharmacotherapy: A Pathophysiologic Approach* (Fifth Edition ed., pp. 1103 - 1117): Appleton & Lange.

Belgrade, M. J. (1999). Opioids for chronic nonmalignant pain. Choosing suitable candidates for long-term therapy. *Postgraduate Medicine, 106*(6), 115.

Benedetti, C., Dickerson, E. D., and Nichols, L. L. (2001). Medical education: a barrier to pain therapy and palliative care. *Journal of Pain and Symptom Management, 21*(5), 360-362.

Berger, J.and O'Brien, W. (1998). Clinical psychology students' self-reported willingness to interact with persons living with HIV. *AIDS Education And Prevention: Official Publication Of The International Society For AIDS Education, 10*(3 (Print)), 199-214.

Bergman, J. J.and Werblun, M. N. (1978). Chronic pain: A review for the family physician. *The Journal of Family Practice, 7*(4), 685-693.

Berina, L. F., Guernsey, B. G., Hokanson, J. A., DoutrÃ, W. H., and Fuller, L. E. (1985). Physician perception of a triplicate prescription law. *American Journal of Hospital Pharmacy., 42*(4), 857-859.

Bernabei, R., Gambassi, G., Lapane, K., Land i, F., Gatsonis, C., Dunlop, R., Lipsitz, L., Steel, K., Mor, V., andfor the SAGE Study Group. (1998). Management of Pain in Elderly Patients With Cancer. *Journal of the American Medical Association, 279*(23), 1877-1882.

Besson, J. M.and Chaouch, A. (1987). Peripheral and spinal mechanisms of nociception. *Physiology Reviews, 67*(1), 67-186.

Bowsher, D., Rigge, M., and Sopp, L. (1991). Prevalence of chronic pain in the British population: a telephone survey of 1037 households. *The Pain Clinic, 4*, 223-230.

Braithwaite, D., Emery, J., S;, D. L., and Sutton, S. (2003). Using the Internet to conduct surveys of health professionals: a valid alternative? *Family Practice, 20*(5), 545-551.

Brattberg, G., Thorslund, M., and Wikman, A. (1989a). The prevalence of pain in a general population. The results of a postal survey in a county of Sweden. *Pain, 37*(2), 215-222.

Brattberg, G., Thorslund, M., and Wikman, A. (1989b). The prevalence of pain in a general population: The results of a postal survey in a county of Sweden. *Pain, 37*, 215–222.

Brecher, E. (1972). *The Harrison Narcotic Act (1914)*. Retrieved Oct 20, 2005, from http://www.druglibrary.org/schaffer/Library/studies/cu/cu8.html

Breen, J. (2002). Transitions in the Concept of Chronic Pain., *Advances in Nursing Science* (Vol. 24, pp. 48): Lippincott Williams & Wilkins -- Nursing.

Brennan, M.and Heit, H. (2005). *Providing Care While Preventing Misuse and Diversion*. Retrieved Aug 14, 2005, from http://www.medscape.com/viewprogram/3635

Brookoff, D. (2000, Sept 15, 2000). *Chronic Pain: 2. The Case for Opioids*. Retrieved Oct 19, 2005, from http://www.hosppract.com/issues/2000/09/brook.htm

Brown, D.and Topcu, M. (2003). Willingness to Participate in Clinical Treatment Research Among Older African Americans and Whites. *Gerontologist, 43*(1), 62-72.

Burchman, S. L.and Pagel, P. S. (1995). Implementation of a formal treatment agreement for outpatient management of chronic nonmalignant pain with opioid analgesics. *Journal of Pain and Symptom Management, 10*(7), 556-563.

Burke, S.and Weitz, M. (2002). Persitent pain in long term care: pathophysiologic mechanisms and treatment strategies. *The Consultant Pharmacist, 17*(suppl B), 10-18.

Burton, A. (2005). Pharmacologic Management of Pain Expert Column: Outpatient Management of Breakthrough Pain. *Medscape Neurology and Neurosurgery, 7*(1).

Caldwell, J. R., Hale, M. E., Boyd, R. E., Hague, J. M., Iwan, T., Shi, M., and Lacouture, P. G. (1999). Treatment of osteoarthritis pain with controlled release oxycodone or fixed combination oxycodone plus acetaminophen added to nonsteroidal antiinflammatory drugs: a double blind, randomized, multicenter, placebo controlled trial. *Journal of Rheumatology, 26*(4), 862-869.

Caldwell, J. R., Rapoport, R. J., Davis, J. C., Offenberg, H. L., Marker, H. W., Roth, S. H., Yuan, W., Eliot, L., Babul, N., and Lynch, P. M. (2002). Efficacy and safety of a once-daily morphine formulation in chronic, moderate-to-severe osteoarthritis pain: results from a randomized, placebo-controlled, double-blind trial and an open-label extension trial. *Journal of Pain and Symptom Management, 23*(4), 278-291.

Canadian Pain Society. (1998). Use of opioid analgesics for the treatment of chronic noncancer pain: A consensus statement and guidelines from the Canadian Pain Society. *Pain Research & Management, Volume 3*(4).

Centre for Addiction and Mental Health. (2005). *Do You Know... Opioids*. Retrieved Nov 2, 2005, from http://www.camh.net/about_addiction_mental_health/opioids_dyk.html

Chapman, C. R.and Nakamura, Y. (1999). A passion of the Soul: an introduction to pain for consciousness researchers. *Consciousness and Cognition, 8*(4), 391-422.

Chapman, C. R.and Stillman, M. (1996). Pathological pain. In K. L (Ed.), *Pain and Touch* (pp. 315-342). New York: Academic Press.

Clark, H. W.and Sees, K. L. (1993). Opioids, chronic pain, and the law. *Journal of Pain and Symptom Management, 8*(5), 297-305.

Clark, M. (2005). *Pain Management: The Benefits and Risks of Opioids*. Retrieved Jun 16, 2005, from http://www.hopkins-arthritis.som.jhmi.edu/mngmnt/opioids.html

Cleeland , C. S., Gonin, R., Baez, L., Loehrer, P., and Pandya, K. J. (1997). Pain and Treatment of Pain in Minority Patients with Cancer: The Eastern Cooperative Oncology Group Minority Outpatient Pain Study. *Annals of Internal Medicine, 127*(9), 813-816.

Collett, B.-J. (2001). Chronic opioid therapy for non-cancer pain. *British Journal of Anaesthesia, 87*(1), 133-143.

Coniam, S. (1989). Prescribing opioids for chronic pain in non-malignant disease. In R. Tywcross (Ed.), *The Edinburgh Symposium on Pain Control and Medical Education. Royal Society of Medicine International Congress and Symposium Series* (Vol. 149, pp. 205-210). London: Royal Society of Medicine.

Consensus Document AAPM APS ASAM. (2001). *Definitions Related to the Use of Opioids for the Treatment of Pain*. Retrieved March 3, 2005, from http://www.asam.org/pain/definitions2.pdf

Couper, M. (2000). Webs Surveys: A review of Issues and Aproaches. *Public Opinion Quarterly, 64*(4), 454-481.

Couper, M., Tourangeau, R., Conrad, F., and Crawford, S. (2004). What they see is what we get: Response options for web surveys. *Social Science Computer Review, 22*(1), 111-127.

Croft, P., Rigby, A., Boswell, R., Schollum, J., and Silman, A. (1993). The prevalence of chronic widespread pain in the general population. *Journal of Rheumatology, 20*, 710-713.

Cronbach, L. J. (1951). Coefficient alpha and the internal structure of tests. Psychometrika. 16, 297-334.

Crook, J., Rideout, E., and Browne, G. (1984). The prevalence of pain complaints in a general population. *Pain, 18*, 299-314.

Crook, J., Tunks, E., Rideout, E., and Browne, G. (1986). Epidemiologic comparison of persistent pain sufferers in a specialty pain clinic and in the community. *Archives of Physical Medicine and Rehabilitation, 67*(7), 451-455.

Davis, M. P., Varga, J., Dickerson, D., Walsh, D., LeGrand, S. B., and Lagman, R. (2003). Normal-release and controlled-release oxycodone: pharmacokinetics, pharmacodynamics, and controversy. *Supportive Care in Cancer, 11*(2), 84-92.

Dickinson, B. D., Altman, R. D., Nielsen, N. H., and Williams, M. A. (2000). Use of opioids to treat chronic, noncancer pain. *Western Journal of Medicine, 172*(2), 107-115.

Dillman, D. (2000). *Mail and internet surveys : the tailored design method* (2nd Ed. ed.). New York: J. Wiley.

Dillman, D. and Bowker, K. (2001). *The Web Questionnaire Challenge to Survey Methodologists*. Lengerich: Pabst Science Publishers.

DiPiro, J., Talbert, R., Yee, G., Matzke, G., Wells, B., and Posey, L. (2005). *Pharmacotherapy: A Pathophysiologic Approach* (6th ed.): Appleton & Lange.

DUAL Corp. (2005). *Pain and HIV*. Retrieved Aug 1, 2005, from http://www.hivpositive.com/f-PainHIV/Pain/PainMenu.html

Dunajcik, L. (1999). Chronic nonmalignant pain. In M. McCaffery & C. L. Pasero (Eds.), *Pain: Clinical manual* (2nd ed., pp. 467-521). St. Louis: Mosby.

Edwards, H., Nash, R., Najman, J., Yates, P., Fentiman, B., Dewar, A., Walsh, A., McDowell, J., and Skerman, H. (2001). Determinants of nurses' intention to administer opioids for pain relief. *Nursing & Health Sciences, 3*(3), 149-159.

Ehrlich, G. (2003). Low back pain. *Bulletin of the World Health Organization, 81*(9), 671-676.

Emons, M. (2003). Persistent nonmalignant pain: implications and opportunities for managed care. *Managed Care, 12*(8 Suppl Improving pain), 2-7.

European Association of Oral Medicine. (2005). *Atypical & Idiopathic Facial Pain*. Retrieved Sept 1, 2005, from http://www.eastman.ucl.ac.uk/~eaom/OM_Handbook/atypical_facial_pain.pdf

Evans, R., Fine, P., Portenoy, R., Argoff, C., Berek, J., Chin, M., Ferrell, B., Fisherman, S., Follett, K., Grabois, M., Houck, C., Hull, R., Knox, K., Koman, L., Kulesz, S., Lambing, C., Savage, S., Thompson, A., Todd, K., and Brown, E. (2003a). *American Medical Assoctiation- Assessing and Treating Pain in Older Adults (1 credit)*. Retrieved March 25, 2005, from http://www.ama-cmeonline.com/pain_mgmt/module05/index.htm

Evans, R., Fine, P., Portenoy, R., Argoff, C., Berek, J., Chin, M., Ferrell, B., Fisherman, S., Follett, K., Grabois, M., Houck, C., Hull, R., Knox, K., Koman, L., Kulesz, S., Lambing, C., Savage, S., Thompson, A., Todd, K., and Brown, E. (2003b). *American Medical Assoctiation- Assessing and Treating Persistent Nonmalignant Pain: An Overview*. Retrieved March 25, 2005, from http://www.ama-cmeonline.com/pain_mgmt/module07/pdf/ama_painmgmt_m7.pdf

Evans, R., Fine, P., Portenoy, R., Argoff, C., Berek, J., Chin, M., Ferrell, B., Fisherman, S., Follett, K., Grabois, M., Houck, C., Hull, R., Knox, K., Koman, L., Kulesz, S., Lambing, C., Savage, S., Thompson, A., Todd, K., and Brown, E. (2003c). *American Medical Assocation- Barriers to Pain Management and Pain in Special Populations (1 credit)*. Retrieved March 25, 2005, from http://www.ama-cmeonline.com/pain_mgmt/module03/02intro/index.htm

Evans, R., Fine, P., Portenoy, R., Argoff, C., Berek, J., Chin, M., Ferrell, B., Fisherman, S., Follett, K., Grabois, M., Houck, C., Hull, R., Knox, K., Koman, L., Kulesz, S., Lambing, C., Savage, S., Thompson, A., Todd, K., and Brown, E. (2003d). *American Medical Assoctiation Pain Management: The Pathophysiology of Pain*. Retrieved March 25, 2005, from http://www.ama-cmeonline.com/pain_mgmt/module01/01cme/index.htm

Fazio, R. H.and Williams, C. J. (1986). Attitude Accessibility as a Moderator of the Attitude-Perception and Attitude-Behavior Relations : An Investigation of the 1984 Presidential Election. *Journal of Personality and Social Psychology, 51*(3), 505-514.

Food and Drug Administration (FDA). (2005). *FDA MedWatch - Palladone (hydromorphone hydrochloride)*. Retrieved July 24, 2005, from http://www.fda.gov/medwatch/SAFETY/2005/safety05.htm#Palladone

Fishbain, D. A., Rosomoff, H. L., and Rosomoff, R. S. (1992). Drug abuse, dependence, and addiction in chronic pain patients. *Clinical Journal of Pain, 8*(2), 77-85.

Fishbein, M. (1967). Attitude and the prediction of behavior. In M. Fishbein (Ed.), *Readings in attitude theory and measurement* (pp. 477-492). New York: Wiley.

Fishbein, M.and Ajzen, I. (1975). *Belief, Attitude, Intention and Behavior: An Introduction to Theory and Research.* Reading: Addison-Wesley.

Fisher, F. (2004a). The Role of Controlled-Release Opioids in the Treatment of Chronic Pain. *Journal of the American Physicians and Surgeons, 9*(2), 52-54.

Fisher, F. B. (2004b). Evaluating the Risks of Unwarranted Prosecution Part 1: The Criminalization of Pain Management. *Journal of American Physicians & Surgeons, 9*(4), 114-117.

Francis, J. E., M; Johnston, M; Walker, A; Grimshaw, J; Foy, R; Kaner, E; Smith, L; Bonetti, D;. (2004). *Constructing Questionnaires Based On The Theory Of Planned Behaviour: A Manual For Health Services Researchers*. Newcastle upon Tyne: Center for Health Services Research.

Frelund, F.and Frelund, C. (1986). Pain in general practice,. *Scandinavian Journal of Primary Health Care, 4*, 97–100.

Frymoyer, J. (1997). *The Adult Spine: Principles and Practice* (2nd ed.). Philadelphia: Lippincott-Raven.

Federation of State Medical Boards (FSMB), (2003). *Model Policy For the Use of Controlled Substances For the Treatment of Pain*.

Gallagher, R. (2004). Opioids in chronic pain management: Navigating the clinical and regulatory challenges. *Journal of Family Practice, 53*(10), S23-31.

Gallagher, R. M. (1999). Primary care and pain medicine. A community solution to the public health problem of chronic pain. *Medical Clinics of North America, 83*(3), 555.

Gardner-Nix, J. (2003). Principles of opioid use in chronic noncancer pain. *Canadian Medical Association Journal, 169*(1), 38-43.

Gerstle, D. S., All, A. C., and Wallace, D. C. (2001). Quality of life and chronic nonmalignant pain. *Pain Management Nursing, 2*(3), 98-109.

Gibbons, F., Gerrard, M., Blanton, H., and Russell, D. (1998). Reasoned action and social reaction: willingness and intention as independent predictors of health risk. *Journal of Personality and Social Psychology, 74*(5), 1164-1180.

Gibbons, F. X.and Gerrard, M. (1995). Predicting Young Adults' Health Risk Behavior. *Journal of Personality and Social Psychology, 69*(3), 505-517.

Gilron, I.and Bailey, J. M. (2003). Trends in opioid use for chronic neuropathic pain: a survey of patients pursuing enrollment in clinical trials. *Canadian Journal of Anaesthesia, 50*(1), 42-47.

Gilson, A. M.and Joranson, D. E. (2001). Controlled substances and pain management: changes in knowledge and attitudes of state medical regulators. *Journal of Pain and Symptom Management, 21*(3), 227-237.

Glajchen, M. (2001). Chronic pain: treatment barriers and strategies for clinical practice. *Journal of the American Board of Family Practice, 14*(3), 211-218.

Godin, G.and Kok, G. (1996). The theory of planned behavior: a review of its applications to health-related behaviors. *American Journal of Health Promotion, 11*(2), 87-98.

Goli, V.and Finley, R. (2005). *Pain Report 7 Focus on Long-Acting Opioids*. Retrieved Aug 14, 2005, from http://www.pain.com/sections/professional/cme_article/articlefull.cfm?id=238

Gordon, D. B. (2003). Nonopioid and adjuvant analgesics in chronic pain management: strategies for effective use. *The Nursing Clinics of North America, 38*(3), 447.

Gourlay, D. L., Heit, H. A., and Passik, S. D. (2004). *Exploring the Misconceptions: Opioids in Pain Management* (CME): Pharma Group.

Granville, L., Pan, C., and Robinson, B. (2005). *Persistent Pain: Evaluation in Primary Practice*. Retrieved Oct 10, 2005, from www.miahonline.org/tools/pain/attachments/Pain_Tool_14_IN.doc

GraphPad, Multicollinearity in multiple regression. Retreived Jan 8, 2007, from http://www.graphpad.com/library/BiostatsSpecial/article_54.htm

Grichnik, K. P.and Ferrante, F. M. (1991). The difference between acute and chronic pain. *Mount Sinai Journal of Medicine, New York, 58*(3), 217-220.

Gureje, O., Von Korff, M., Simon, G. E., and Gater, R. (1998). Persistent pain and well-being: a World Health Organization Study in Primary Care. *The Journal of the American Medical Association, 280*(2), 147-151.

Hagger, M. S., Chatzisarantis, N. L. D., and Biddle, S. J. H. (2002). A Meta-Analytic Review of the Theories of Reasoned Action and Planned Behavior in Physical Activity: Predictive Validity and the Contribution of Additional Variables. *Journal of Sport & Exercise Psychology, 24*(1), 3-32.

Hale, M. E., Fleischmann, R., Salzman, R., Wild, J., Iwan, T., Swanton, R. E., Kaiko, R. F., and Lacouture, P. G. (1999). Efficacy and safety of controlled-release versus immediate-release oxycodone: randomized, double-blind evaluation in patients with chronic back pain. *Clinical Journal of Pain, 15*(3), 179-183.

Hoffmann, D.and Tarzian, A. (2003). Achieving the Right Balance in Oversight of Physician Opioid Prescribing for Pain: The Role of State Medical Boards. *Journal of Law, Medicine & Ethics,, 31*, 21-40.

James, F., Large, R. G., Bushnell, J. A., and Wells, J. E. (1991). Epidemiology of pain in New Zealand. *Pain, 44*, 279–283.

James, F. R.and Large, R. G. (1992). Chronic pain and the use of health services. *The New Zealand Medical Journal, 105*(934), 196-198.

Jamison, R., Gintner, L., Rogers, J., and Fairchild, D. (2002). Disease Management for Chronic Pain: Barriers of Program Implementation With Primary Care Physicians. *Pain Medicine, 3*(2), 92.

Jassen Pharmaceutica Products L.P. (2003). *Duragesic (Fentanyl Transdermal System) [package insert]*.

Joint Commission on Accreditation of Healthcare Organizations (JCAHO), (2000). *Pain Assessment and Management: An Organizational Approach*. Oakbrook Terrance: JCAHO.

Joranson, D., Gilson, A., Dahl, J., and Haddox, J. (2002). Pain management, controlled substances, and state medical board policy: a decade of change, *Journal of Pain and Symptom Management* (Vol. 23, pp. 138-147).

Joranson, D. E., Cleeland , C. S., Weissman, D. E., and Gilson, A. M. (1992). Opioids for Chronic Cancer and Non-Cancer Pain: A Survey of State Medical Board Members. *Federation Bulletin: The Journal of Medical Licensure and Discipline, 79*, 15-49.

Joranson, D. E.and Gilson, A. M. (1996). Improving pain management through policy making and education for medical regulators. *Journal of Law, Medicine & Ethics, 24*(4), 344-347.

Joranson, D. E. and Gilson, A. M. (1997). State Intractable Pain Policy: Current Status. *APS Bulletin, 7*(2), 7-9.

Joranson, D. E. and Gilson, A. M. (1998). Regulatory barriers to pain management. *Seminars in Oncology Nursing, 14*(2), 158-163.

Joranson, D. E., Ryan, K. M., Gilson, A. M., and Dahl, J. L. (2000). Trends in medical use and abuse of opioid analgesics. *JAMA, 283*(13), 1710-1714.

Kantowitz, B. H., Lee, J.D., Becker, C.A., Bittner, A.C., Kantowitz, S.C., Hanowski, R.J., Kinghorn, R.A., McCauley, M.E., Sharkey, T.J., McCallum, M.C., and Barlow, S.T. (1997). *Development of Human Factors Guidelines for Advanced Traveler Information Systems and Commercial Vehicle Operations* (No. FHWA-RD-96-143). Seattle: Office of Safety and Traffic Operations R&D-Federal Highway Administration.

Karpman, R. R., Del Mar, N., and Bay, C. (1997). Analgesia for emergency centers' orthopaedic patients: does an ethnic bias exist? *Clinical Orthopaedics and Related Research*(334), 270-275.

Kellerman, S. E. and Herold, J. (2001). Physician response to surveys. A review of the literature. *American Journal of Preventive Medicine., 20*(1), 61-67.

Kohlmann, T. (1991). Schmerzen in der Lübecker Bevölkerung. Ergebnisse einer bevölkerungsepidemiologischen Studie. *Schmerz, 5*, 208-213.

Kumar, K.and Demeria, D. (2003). The Role of Opioids in the Treatment of Chronic Nonmalignant Pian in the Elderly. *Annals of Long-Term Care, 11*(3).

Lambert, B. L., Salmon, J. W., Stubbings, J., Gilomen-Study, G., Valuck, R. J., and Kezlarian, K. (1997). Factors associated with antibiotic prescribing in a managed care setting: an exploratory investigation. *Social Science & Medicine, 45*(12), 1767-1779.

Lauretti, G. R., Oliveira, G. M., and Pereira, N. L. (2003). Comparison of sustained-release morphine with sustained-release oxycodone in advanced cancer patients. *British Journal of Cancer, 89*(11), 2027-2030.

Lee, P. (1994). The economic impact of musculoskeletal disorders. *Quality of Life Research, 3 Suppl 1*, S85-91.

Leece, P., Bhandari, M., Sprague, S., Swiontkowski, M., EH;, S., Tornetta, P., Devereaux, P., and Guyatt, G. (2004). Internet Versus Mailed Questionnaires: A Controlled Comparison (2). *Journal of Medical Internet Research, 6*(4), e39.

Limbert, C. and Lamb, R. (2002). Doctors' use of clinical guidelines: two applications of the Theory of Planned Behaviour. *Psychology, Health & Medicine, 7*(3), 301-310.

Loesser, J. D. (1999). Economic implications of pain management. *Acta Anaesthesiologica Scandinavica, 43*, 957-959.

Ma¨ke´la¨, M. and Helio¨vaara, M. (1991). Prevalence of primary fibromyalgia in the Finnish population. *British Medical Journal, 303*, 216–219.

MacLean, C. H., Knight, K., Paulus, H., Brook, R. H., and Shekelle, P. G. (1998). Costs attributable to osteoarthritis. *Journal of Rheumatology, 25*(11), 2213-2218.

Madden, T. J., Ellen, P. S., and Ajzen, I. (1992). A comparison of the theory of planned behavior and the theory of reasoned action. *Personality and Social Psychology Bulletin, 18*(1), 3-9.

Magni, G., Carldieron, C., Rigatti-Lunchini, S., and Merskey, H. (1990). Chronic musculoskeletal pain and depressive symptoms in the general population. An analysis of the 1st National Health and Nutrition Examination Survey data. *Pain, 43*, 29-307.

Magni, G., Carldieron, C., Rigatti-Lunchini, S., and Merskey, H. (1992). Chronic abdominal pain and depression: Epidemiologic findings in the United States. Hispanic health and nutrition examination survey. *Pain*, 77-85.

Magni, G., Marchetti, M., Moreschi, C., Merskey, H., and Luchini, S. (1993). Chronic musculoskeletal pain and depressive symptoms in the National Health and Nutrition Examination. I. Epidemiologic follow-up study. *Pain, 53*(2), 163-168.

Maniadakis, N.and Gray, A. (2000). The economic burden of back pain in the UK. *Pain, 84*(1 (Print)), 95-103.

Marcus, D. (2000). Treatment of nonmalignant chronic pain. *American Family Physician, 61*(5), 1331-1338,1345-1336.

Marcus, D. (2002). Managing Chronic Pain in the Primary Care Setting. *American Family Physician, 66*(1), 36.

Marcus, D. (2003). Tips for managing chronic pain: Implementing the latest guidelines. *Postgraduate Medicine, 113*(4), 49-66,98.

Marks, R.and Sachar, E. (1973). Under treatment of medical inpatients with narcotic analgesics. *Annals of Internal Medicine, 78*(2), 173-181.

Mashburn, J. H. (2004). *Using the Theory of Planned Behavior to predict Texas community pharmacists' willingness to provide sterile syringes to known or suspected intravenous drug users.*, Univ Microfilms International.

McCarberg, B. (2004). Contemporary management of chronic pain disorders. *Journal of Family Practice, 53*(10), S11-22.

McIntosh, H. (1991). Regulatory barriers take some blame for pain under treatment. *Journal of the National Cancer Institute, 83*(17), 1202-1204.

McMahon, S., Iwamoto, M., Massoudi, M., Yusuf, H., Stevenson, J., David, F., Chu, S., and Pickering, L. (2003). Comparison of e-mail, fax, and postal surveys of pediatricians. *Pediatrics, 111*(4 Pt 1), e299-303.

McPherson, M., Canaday, B., Heit, H., and Rospond, R. (2004). *A Pharmacist's Guide to the Clinical Assessment and Management of Pain*. Washington, DC: APhA.

Melzack, R.and Wall, P. (1965). Pain mechanisms: a new theory. *Science, 150*(699 (Print)), 971-979.

Merskey, H.and Bogduk, N. (1994). *Classification of Chronic Pain* (2nd ed.). Seattle: International Association for the Study of Pain Press.

Millstein, S. G. (1996). Utility of the theories of reasoned action and planned behavior for predicting physician behavior: a prospective analysis. *Health psychology : official journal of the Division of Health Psychology, American Psychological Association., 15*(5), 398-402.

Montano, D.and Kasprzyk, D. (2002). The Theory of Resaoned Action and The Theory of Planned Behavior. In K. Glanz, B. K. Rimer & F. M. Lewis (Eds.), *Health Behavior and Health Education : Theory, Research, and Practice* (3rd ed., pp. 67-96). San Francisco: Jossey-Bass.

Morley-Forster, P. K., Clark, A. J., Speechley, M., and Moulin, D. E. (2003). Attitudes toward opioid use for chronic pain: a Canadian physician survey. *Pain research & management, 8*(4), 189-194.

Motsko, S, Rascati, K; Busti, A, Wilson, J, Barner, J, Lawson, K, and Worchel, J.. (2006). Temporal Relationship between Use of NSAIDs, Including Selective COX-2 Inhibitors, and Cardiovascular Risk. *Drug Safety 29(7) 621-632*.

Moulin, D. E.and Iezzi, A. (1996). Randomised trial of oral morphine for chronic non-cancer pain. *Lancet, 347*(8995), 143.

Nash, R., Edwards, H., and Nebauer, M. (1993). Effect of attitudes, subjective norms and perceived control on nurses' intention to assess patients' pain. *Journal of Advanced Nursing, 18*(6), 941-947.

National Center on Addiction and Substance Abuse at Columbia University. (2003). *CASA's analysis of ARCOS (Automation of Reports and Consolidated Orders System) data [Data file].* Washington, DC: U.S. Department of Justice, Drug Enforcement Administration, Diversion Control Program.

National Drug Intelligence Center. (2001). *National drug threat assessment 2002: Pharmaceuticals*. Retrieved Nov 25, 2005, from http://www.usdoj.gov/ndic/pubs/716/716p.pdf

National Pharmaceutical Council. (2001). *Pain: Current Understanding of Assessment, Management, and Treatment* (Monograph): Joint Commission on Accreditation of Healthcare Organization.

New Hampshire Medical Society. (1998). *Guidelines for the Use of Controlled Substances in the Treatment of Pain*. Retrieved Oct 11, 2005, from http://www.nhms.org/

Ng, B., Dimsdale, J. E., Rollnik, J. D., and Shapiro, H. (1996). The effect of ethnicity on prescriptions for patient-controlled analgesia for post-operative pain. *Pain, 66*(1), 9-12.

Noursis, M. J. (2005). SPSS 13.0 Guide to data analysis. Upper Saddle River, NJ: Prentice Hall.

Notani, A. S. (1998). Moderators of Perceived Behavioral Control's Predictiveness in the Theory of Planned Behavior: A Meta-Analysis. *Journal of Consumer Psychology, 7*(3), 247.

Novak, S., Nemeth, W. S., and Lawson, K. A. (2004). Trends in Medical Use and Abuse of Sustained-Release Opioid Analgesics: A Revisit. *Pain Medicine, 5*(1), 59-65.

Nussmeier, N. A., Whelton, A. A., Brown, M. T., Langford, R. M., Hoeft, A., Parlow, J. L., Boyce, S. W., and Verburg, K. M. (2005). Complications of the COX-2 inhibitors parecoxib and valdecoxib after cardiac surgery. *New England Journal of Medicine, 352*(11), 1081-1091.

Olmsted, M., Murphy, J., McFarlane, E., and Hill, C. (2005). *Evaluating Methods for Increasing Physician Survey Cooperation*. Retrieved June 6, 2005, from www.RTI.org/AAPOR

Oneschuk, D., Hanson, J., and Bruera, E. (2000). An International Survey of Undergraduate Medical Education in Palliative Medicine. *Journal of Pain and Symptom Management, 20*(3), 174-179.

Ortho-McNeil Pharmaceutical. (1999). *National Pain Survey*. Retrieved Sept 27, 2005, from http://www.chiro.org/LINKS/FULL/1999_National_Pain_Survey.html

Osgood, C. E., Suci, G. J., and Tannenbaum, P. H. (1957). *The measurement of meaning.*: University of Illinois Press.

Otis, J.and Fudin, J. (2005). *Use of Long-Acting Opioids for the Management of Chronic Pain*. Retrieved Jun 14, 2005, from http://www.uspharmacist.com/index.asp?page=ce/10163/default.htm

Pain & Policy Studies Group. (2004). *Achieving Balance in State Pain Policy: A Progress Report Card*. Retrieved Dec 11, 2005, from http://www.medsch.wisc.edu/painpolicy/2003_balance/prc2003.pdf

Parrott, T. (2002). Pain Management in Primary-Care Medical Practice. In J. Satterthwaithe & J. Tollison (Eds.), *Practical Pain Management* (pp. 729-759). Philadelphia: Lippincott Williams & Wilkins.

PDR Health. (2005). *Drug Information*. Retrieved August 8, 2005, from http://www.pdrhealth.com/drug_info/index.html

Peat, S., Sweet, P., Miah, Y., Barklamb, M., and Larsen, U. (1999). Assessment of analgesia in human chronic pain. Randomized double-blind crossover study of once daily repro-dose morphine versus MST continus. *European Journal of Clinical Pharmacology, 55*(8), 577-581.

Perry, S.and Heidrich, G. (1982). Management of pain during debridement: a survey of U.S. burn units. *Pain, 13*(3), 267-280.

Petty, R.and Cacioppo, J. (1981). *Attitudes and Persuasion: Classic and Contemporary Approaches*. Dubuque: Wm. C. Brown Company.

Pinsky, I., Labouvie, E., and Laranjeira, R. (2004). Willingness and alternatives to drunk driving among young people from São Paulo city, Brazil. *Revista Brasileira de Psiquiatria, 26*(4), 234-241.

Polit, D. F.and Hungler, B. P. (1995). *Nursing Research: Principles and Methods* (6th ed.). New York: Lipincott.

Ponte, C. D.and Johnson-Tribino, J. (2005). Attitudes and knowledge about pain: an assessment of West Virginia family physicians. *Family Medicine, 37*(7), 477-480.

Portenoy, R. (1994). Opioid therapy for nonmalignant pain. In H. Fields & J. Liebkind (Eds.), *Pharmacological Approaches to the Treatment of Chronic Pain: New Concepts and Critical Issues* (Vol. 1, pp. 247-287). Seattle: International Association for the Study of Pain.

Portenoy, R. K. (1996a). Opioid therapy for chronic nonmalignant pain: clinician's perspective. *Journal of Law, Medicine & Ethics, 24*(4), 296-309.

Portenoy, R. K. (1996b). Opioid therapy for chronic nonmalignant pain: a review of the critical issues. *Journal of Pain and Symptom Management, 11*(4), 203-217.

Portenoy, R. K. (2000). Current pharmacotherapy of chronic pain. *Journal of Pain and Symptom Management, 19*(1 Suppl), S16-20.

Porter, J.and Jick, H. (1980). Addiction rare in patients treated with narcotics. *New England Journal of Medicine, 302*(2), 123.

Potter, M., McColskey, J., and Schneider, J. (2004). *The Law and Controlled Substances Prescribing*. Stamford: PharmaCom Group.

Potter, M., Schafer, S., Gonzalez-Mendez, E., Gjeltema, K., Lopez, A., Wu, J., Pedrin, R., Cozen, M., Wilson, R., Thom, D., and Croughan-Minihane, M. (2001). Opioids for chronic nonmalignant pain. Attitudes and practices of primary care physicians in the UCSF/Stanford Collaborative Research Network. University of California, San Francisco., *Journal of Family Practice* (Vol. 50, pp. 145-151).

Potter, R. G.and Jones, J. M. (1992). The evolution of chronic pain among patients with musculoskeletal problems: a pilot study in primary care. *British Journal of General Practice, 42*(364), 462-464.

Praemer, A., Furnes, S., and Rice, D. (1992). *Musculoskeletal conditions in the United States*. Rosemont: AAUS.

Probst, J., Moore, C., Baxley, E., and Lammie, J. (2002). Rural-urban differences in visits to primary care physicians. *Family Medicine, 34*(8), 609-615.

Purdue Pharma LP. (2003). *OxyContin (oxycodone) [package insert] Black Box warning section*. Stamford.

Ralston, D. (1996). Pain Management: Texas Legislative and Regulatory Update. *Journal of Law, Medicine & Ethics, 24*(4), 328-337.

Raziano, D., Jayadevappa, R., Valenzula, D., Weiner, M., and Lavizzo-Mourey, R. (2001). E-mail versus conventional postal mail survey of geriatric chiefs. *Gerontologist, 41*(6), 799-804.

Rhodes, R.and Courneya, K. (2003). Modelling the theory of planned behaviour and past behaviour. *Psychology, Health & Medicine, 8*(1), 57-69.

Robbins, L.and Akbarnia, H. (2000). *Long-acting opioids for severe, refractive chronic daily headache: sustained-release*. Retrieved Oct 19, 2005, from http://www.headachedrugs.com/archives/la_opioids2.html

Rosenberg, M. J., Hovland , C. I., McGuire, W. J., Abelson, R. P., and Brehm, J. W. (1960). *Attitude organization and change: An analysis of consistency among attitude components. (Yales studies in attitude and communication. Vol. III.).* New Haven: Yale University Press.

Roth, S. H. (2002). A new role for opioids in the treatment of arthritis. *Drugs, 62*(2), 255-263.

Roth, S. H., Fleischmann, R. M., Burch, F. X., Dietz, F., Bockow, B., Rapoport, R. J., Rutstein, J., and Lacouture, P. G. (2000). Around-the-clock, controlled-release oxycodone therapy for osteoarthritis-related pain: placebo-controlled trial and long-term evaluation. *Archives of Internal Medicine, 160*(6), 853-860.

Salzman, R. T., Roberts, M. S., Wild, J., Fabian, C., Reder, R. F., and Goldenheim, P. D. (1999). Can a controlled-release oral dose form of oxycodone be used as readily as an immediate-release form for the purpose of titrating to stable pain control? *Journal of Pain and Symptom Management, 18*(4), 271-279.

San Francisco AIDS Foundation. (2005). Glossary Retrieved March 30, 2005, from http://www.sfaf.org/glossary/

Sanders, S., Harden, R., Benson, S., and Vicente, P. (1999). Clinical practice guidelines for chronic non-malignant pain syndrome patients II: An evidence-based approach., *Journal of Back & Musculoskeletal Rehabilitation* (Vol. 13): IOS Press.

Savage, S. R. (1999). Opioid therapy of chronic pain: Assessment of consequences. *Acta Anaesthesiologica Scandinavica, 43*(9), 909-917.

Savage, S. R. (2002). Assessment for addiction in pain-treatment settings. *Clinical Journal of Pain, 18*(4 Suppl), S28-38.

Scanlon, M.and Chugh, U. (2004). Exploring Physicians Comfort Level with Opioids for Chronic Noncancer Pain. *Pain Research & Management, 9*(4), 195-201.

Schnitzer, T. J. (1998). Non-NSAID pharmacologic treatment options for the management of chronic pain. *The American Journal of Medicine, 105*(1B), 45S-52s.

Schnitzer, T. J., Gray, W. L., Paster, R. Z., and Kamin, M. (2000). Efficacy of tramadol in treatment of chronic low back pain. *Journal of Rheumatology, 27*(3), 772-778.

Sheppard, B. H., Hartwick, J., and Warshaw, P. R. (1988). The Theory of Reasoned Action: A Meta-Analysis of Past Research with Recommendations for Modifications and Future Research. *Journal of Consumer Research, 15*(3), 325.

Simpson, R. K., Jr, Edmondson, E. A., Constant, C. F., and Collier, C. (1997). Transdermal fentanyl as treatment for chronic low back pain. *Journal of Pain and Symptom Management, 14*(4), 218-224.

Sloan, P. A., Montgomery, C., and Musick, D. (1998). Medical Student Knowledge of Morphine for the Management of Cancer Pain. *Journal of Pain and Symptom Management, 15*(6), 359-364.

Solomon, S. D., McMurray, J. J. V., Pfeffer, M. A., Wittes, J., Fowler, R., Finn, P., Anderson, W. F., Zauber, A., Hawk, E., and Bertagnolli, M. (2005). Cardiovascular risk associated with celecoxib in a clinical trial for colorectal adenoma prevention. *New England Journal of Medicine, 352*(11), 1071-1080.

SPSS for Microsoft Windows, Release 13.0 2005

Sternbach, R. (1986). Survey of pain in the United States: the Nuprin pain report. *Clinical Journal of Pain, 2*, 49–53.

Stevenson, F. A., Greenfield, S. M., Jones, M., Nayak, A., and Bradley, C. P. (1999). GPs' perceptions of patient influence on prescribing. *Family Practice, 16*(3), 255-261.

Stewart, W. F., Ricci, J. A., Chee, E., Morganstein, D., and Lipton, R. (2003). Lost Productive Time and Cost Due to Common Pain Conditions in the US Workforce. *JAMA, 290*(18), 2443-2454.

Stoddard, S., Jans, L., Ripple, J., and Kraus, L. (1998). *Chartbook on Work and Disability in the United States*. Washington, D.C: U.S. National Institute on Disability and Rehabilitation Research.

Substance Abuse and Mental Health Services Administration. (2004). *Results from the 2003 National Survey on Drug Use and Health: National findings* (No. DHHS Pub. No. (SMA) 04-3964). Rockville: U.S. Department of Health and Human Services, Office of Applied Studies.

Sunshine, A.and Olson, N. (1989). Non-narcotic analgesics. In P. Wall & R. Melzack (Eds.), *Textbook of Pain* (pp. 670-685). New York: Churchill Livingstone.

Tabachnick, B.and Fidell, L. (2001). *Using Multivariate Statistics* (4th ed.). Boston: Allyn and Bacon.

Tamayo-Sarver, J. H., Dawson, N. V., Hinze, S. W., Cydulka, R. K., Wigton, R. S., Albert, J. M., Ibrahim, S. A., and Baker, D. W. (2003). The Effect of Race/Ethnicity and Desirable Social Characteristics on Physicians' Decisions to Prescribe Opioid Analgesics. *Acad Emerg Med, 10*(11), 1239-1248.

Texas Medical Board. (2005). Texas State Board of Medical Examiners Policy on Treatment of Pain. *TSBME Newsletter, 15*(1).

Texas Medical Board. (2006). *Texas Physician Demographic Information*. Retrieved April 2, 2006, from http://www.tmb.state.tx.us/agency/statistics/demo/docs/docdemo.php

Thomas, W. I.and Znaniecki, F. (1927). *The Polish peasant in Europe and America. (2 vols.) (2d ed.).* Knopf.

Thomsen, A. B., Sorensen, J., Sjogren, P., and Eriksen, J. (2001). Economic Evaluation of Multidisciplinary Pain Management in Chronic Pain Patients: A Qualitative Systematic Review. *Journal of Pain and Symptom Management, 22*(2), 688-698.

Thurstone, L. (1931). The measurement of Attitudes. *Journal of Abnormal and Social Psychology, 26*, 249-269.

Todd, K. H., Deaton, C., D'Adamo, A. P., and Goe, L. (2000). Ethnicity and analgesic practice. *Annals of Emergency Medicine, 35*(1), 11-16.

Todd, K. H., Samaroo, N., and Hoffman, J. R. (1993). Ethnicity as a risk factor for inadequate emergency department analgesia. *The Journal of the American Medical Association, 269*(12), 1537-1539.

Triandis, H. C. (1980). Values, attitudes, and interpersonal behavior. *Nebraska Symposium on Motivation., 27*, 195-259.

Turk, D.and Brody, M. (1992). *What position do APS's physician members take on chronic opioid therapy?* : APS.

Turk, D.and Okifuji, A. (2000). Pain terms and taxonomies of pain. In e. a. Loesser JD; Butler SH; Chapman CR (Ed.), *Bonica's Management of Pain* (3rd ed., pp. 17-25). Philadelphia: Lippincott, Williams & Wilkins.

Turk, D. C. (1996). Clinicians' attitudes about prolonged use of opioids and the issue of patient heterogeneity. *Journal of Pain and Symptom Management, 11*(4), 218-230.

Turk, D. C., Brody, M. C., and Okifuji, E. A. (1994). Physicians' attitudes and practices regarding the long-term prescribing of opioids for non-cancer pain. *Pain, 59*(2), 201-208.

Turk, D. C.and Okifuji, A. (1997). What factors affect physicians' decisions to prescribe opioids for chronic noncancer pain patients? *The Clinical Journal Of Pain, 13*(4), 330-336.

U.S. Department of Health and Human Services. (2002). *Results from the 2001 National Household Survey on Drug Abuse* (No. DHHS Pub No. (SMA) 02-3759). Rockville: U.S. Department of Health and Human Services, Office of Applied Studies.

U.S. Department of Health and Human Services. (2005). *National Ambulatory Medical Survey, 2003*. Retrieved Sept 1, 2005, from http://www.cdc.gov/nchs/about/major/ahcd/ahcd1.htm

U.S. Drug Enforcement Administration. (2003). *The Myth of the "Chilling Effect" Doctors Operating Within Bounds of Accepted Medical Practice Have Nothing to Fear From DEA*. Retrieved Nov 10, 2005, from http://www.usdoj.gov/dea/pubs/pressrel/pr103003p.html

U.S. Drug Enforcement Administration. (2005). *Controlled Substances Act*. Retrieved Nov 15, 2005, from http://www.usdoj.gov/dea/agency/csa.htm

Urban, B. J., France, R. D., Steinberger, E. K., Scott, D. L., and Maltbie, A. A. (1986). Long-term use of narcotic/antidepressant medication in the management of phantom limb pain. *Pain, 24*(2), 191-196.

van Ryn, M.and Burke, J. (2000). The effect of patient race and socio-economic status on physicians' perceptions of patients. *Social Science & Medicine, 50*(6), 813-828.

Verhaak, P., Kerssens, J., Dekker, J., Sorbi, M., and Bensing, J. (1998). Prevalence of chronic benign pain disorder among adults: a review of the literature. *Pain, 77*(3), 231-239.

Veterans Health Administration, Department of Defense . (2003). *VA/DoD clinical practice guideline for the management of opioid therapy for chronic pain*. Washington, DC: Veterans Health Administration, Department of Defense.

Von Gunten, C. F.and Von Roenn, J. H. (1994). Barriers to pain control: ethics & knowledge. *Journal of Palliative Care, 10*(3), 52-54.

Von Korff, M., Wagner, E. H., Dworkin, S. F., and Saunders, K. W. (1991). Chronic pain and use of ambulatory health care. *Psychosomatic Medicine, 53*(1), 61-79.

Von Roenn, J. H., Cleeland , C. S., Gonin, R., Hatfield, A. K., and Pandya, K. J. (1993). Physician attitudes and practice in cancer pain management. A survey from the Eastern Cooperative Oncology Group. *Annals of Internal Medicine, 119*(2), 121-126.

VonKorff, M., Dworkin, S. F., and Resche, L. L. (1990). Graded chronic pain status: an epidemiological evaluation. *Pain, 40*(3), 279-291.

VonKorff, M., Dworkin, S. F., and Resche, L. L. (1993). First onset of common pain symptoms: a prospective study of depression as a risk factor. *Pain, 55*, 251-258.

VonKorff, M., Dworkin, S. F., Resche, L. L., and Kruger, A. (1988). An epidemiologic comparison of pain complaints. *Pain, 32*(2), 173-183.

Walker, E., Grimshaw M, and Armstrong M. (2001). Salient beliefs and intetnions to prescribe antibiotics for patients with sore throat. *British Journal of Health Psychology, 6*, 347-360.

Washington State Department of Labor and Industries. (2002). *Guidelines for outpatient prescription of oral opioids for injured workers with chronic, noncancer pain.*

Weiner, K. (2001). *Pain is an Epidemic*. Retrieved Dec 17, 2004, from http://www.aapainmanage.org/literature/Articles/PainAnEpidemic.pdf

Weinstein, S. M., Laux, L. F., Thornby, J. I., Lorimor, R. J., Hill, C. S., Jr, Thorpe, D. M., and Merrill, J. M. (2000). Physicians' attitudes toward pain and the use of opioid analgesics: results of a survey from the Texas Cancer Pain Initiative. *Southern medical journal, 93*(5), 479-487.

Weinstein, S. M., Laux, L. F., Thornby, J. I., Lorimor, R. J., Hill, C. S., Jr, Thorpe, D. M., and Merrill, J. M. (2000a). Medical students' attitudes toward pain and the use of opioid analgesics: implications for changing medical school curriculum. *Southern Medical Journal, 93*(5), 472-478.

Weinstein, S. M., Laux, L. F., Thornby, J. I., Lorimor, R. J., Hill, C. S., Jr, Thorpe, D. M., and Merrill, J. M. (2000b). Physicians' attitudes toward pain and the use of opioid analgesics: results of a survey from the Texas Cancer Pain Initiative. *Southern Medical Journal, 93*(5), 479-487.

Weisse, C. S., Sorum, P. C., and Dominguez, R. E. (2003). The influence of gender and race on physicians' pain management decisions. *Journal of Pain, 4*(9), 505-510.

Weisse, C. S., Sorum, P. C., Sanders, K. N., and Syat, B. L. (2001). Do Gender and Race Affect Decisions About Pain Management? *JGIM: Journal of General Internal Medicine, 16*(4), 211-217.

Weissman, D. E.and Haddox, J. D. (1989). Opioid pseudoaddiction--an iatrogenic syndrome. *Pain, 36*(3), 363-366.

Weissman, D. E., Joranson, D. E., and Hopwood, M. B. (1991). Wisconsin physicians' knowledge and attitudes about opioid analgesic regulations. *Wisconsin Medical Journal, 90*(12), 671-675.

Wisconsin Medical Society: Task Force on Pain Management. (2004). Guidelines for the Assessment and Management of Chronic Pain. *Wisconsin Medical Journal, 103*(3), 13-43.

Woolf, C. (1993). The pathophysiology of peripheral neuropathic pain-abnormal peripheral input and abnormal peripheral central processing. *Acta Neurologica Scandinavica, Suppl*(58), 125-130.

World Health Organization. (1990). *Cancer, pain relief and palliative care* (No. 408). Geneva: World Health Organization.

Zacny, J., Bigelow, G., Compton, P., Foley, K., Iguchi, M., and Sannerud, C. (2003). College on Problems of Drug Dependence taskforce on prescription opioid non-medical use and abuse: position statement. *Drug and Alcohol Dependence, 69*(3), 215-232.

Zagari, M. J., Mazonson, P. D., and Longton, W. C. (1996). Pharmacoeconomics of chronic nonmalignant pain. *PharmacoEconomics, 10*(4), 356-377.

Zenz, M., Strumpf, M., and Tryba, M. (1992). Long-term oral opioid therapy in patients with chronic nonmalignant pain. *Journal of Pain and Symptom Management, 7*(2), 69-77.

VITA

Esmond Donlee Nwokeji was born in London, England on March 11, 1972, the first son of Don A. Nwokeji, RPh and Cathie M. Nwokeji. Esmond graduated from Health Careers High School, San Antonio, Texas, in 1990. He received a Bachelor of Arts in Biology, in 1996, and a Master of Business Administration, in 1998, from St. Edward's University in Austin, Texas. While completing his degrees, he worked in health information management, quality improvement in a managed care organization, analytical systems support for a retirement insurance organization, and quality compliance at a contract research organization. Subsequently, he was employed as a business development manager at the Texas Academy of Family Physicians. In August of 2002 he started graduate school in the Division of Pharmacy Administration at University of Texas.

Permanent Address: 4243 Goshen Pass, San Antonio, Texas 78230

This dissertation was typed by the author.